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Nuclear Material Events Database

Annual Report

Fiscal Year 2021

Prepared for the U.S. Nuclear Regulatory Commission
by Idaho National Laboratory (INL/LTD-21-65151)

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ABSTRACT

This report presents information on trending and analysis of incidents/accidents (events) reported to the Nuclear Regulatory Commission (NRC) that involve radioactive material. The events are reported by NRC licensees, Agreement States, and non-licensees, and are recorded in the NRC's Nuclear Material Events Database. The reported events are classified into categories based on event reporting requirements defined in Title 10 of the Code of Federal Regulations. The categories in this report are (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, and (8) Other.

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ACRONYMS

ALARA	as low as reasonably achievable
ALI	annual limit on intake
AO	abnormal occurrence
AU	authorized user
CFR	Code of Federal Regulations
CT	computed tomography
DDE	deep dose equivalent
DE	dose equivalent
DOT	Department of Transportation
EDE	effective dose equivalent
EQP	Equipment
EXP	Radiation Overexposure
GTCC	greater than class C
HLW	high level waste
HPT	health physics technician
IAEA	International Atomic Energy Agency
INL	Idaho National Laboratory
LAS	Lost/Abandoned/Stolen Material
LKS	Leaking Sealed Source
LS	least squares
MED	Medical
NA	not applicable
NMED	Nuclear Material Events Database
NMT	nuclear medicine technologist
NR	not recovered
NRC	Nuclear Regulatory Commission
OTH	Other
REAC/TS	Radiation Emergency Assistance Center/Training Site
RLM	Release of Licensed Material or Contamination
RSO	radiation safety officer
SDE	shallow dose equivalent
SNM	special nuclear material
SSE	error sum of squares

SSR	regression sum of squares
SST	total sum of squares
TEDE	total effective dose equivalent
TRS	Transportation

EXECUTIVE SUMMARY

The Nuclear Regulatory Commission's (NRC) Nuclear Material Events Database (NMED) contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The reported events are classified based on reporting requirements defined by Title 10 of the Code of Federal Regulations. The event reports are evaluated to identify statistically significant trends and events of higher significance (referred to as significant events in this report).

The significant events that occurred in Fiscal Year 2021 are summarized below. Some of these events are considered potential Abnormal Occurrences (AOs) until they complete NRC's formal AO determination process and are reported in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that a single event may be listed in more than one event type category.

Lost/Abandoned/Stolen Radioactive Sources/Material Events

Fourteen significant events occurred involving the loss of 21 Category 1-3 sources as defined by the International Atomic Energy Agency's *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. No Category 1 sources, sixteen Category 2 sources, and five Category 3 sources were lost; all of which were recovered except one Category 3 source.

Regarding the fourteen significant events:

- Nine of the events involved the loss of Category 2 sources (16 total). All of these were radiography sources and were subsequently recovered. Eight of these events involved sources lost during shipping. In the ninth event, a radiography exposure device containing a source was left unsecured in a truck that was dropped off at a repair facility.
- Five of the events involved the loss of Category 3 sources (five total). All of the sources were lost during shipping. All but one of the sources were recovered.

Medical Events

Seven significant events occurred, all of which were classified as potential Abnormal Occurrences. Three of the events involved Y-90 microsphere doses delivered to unintended sites. In two events, therapeutic doses of I-131 were administered instead of the intended I-123 diagnostic studies. In the remaining two events, prostate brachytherapy seeds were implanted into wrong locations.

Radiation Overexposure Events

No significant events occurred.

Release of Licensed Material or Contamination Events

No significant events occurred.

Leaking Sealed Source Events

No significant events occurred.

Equipment Events

No significant events occurred.

Transportation Events

No significant events occurred.

Other Events

One significant event occurred, which was also classified as a potential Abnormal Occurrence. In this event, an embryo/fetus received a radiation dose when a patient who was unknowingly pregnant received an I-131 therapy treatment.

Nuclear Material Events Database Annual Report: Fiscal Year 2021

1. INTRODUCTION

1.1 Overview and Objectives

Nuclear material event reports are evaluated to identify statistically significant trends and significant events. The reported information aids in understanding why the events occurred and in identifying any actions necessary to improve the effectiveness of the nuclear material regulatory program.

A database for tracking nuclear material events was developed by the Nuclear Regulatory Commission (NRC) in 1981. In 1993, using existing material events databases, the NRC developed a new and more comprehensive database for tracking material events. This database, designated the Nuclear Material Events Database (NMED), contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States, and non-licensees. The database is maintained by Idaho National Laboratory (INL) and contains approximately 27,000 records of material events submitted to the NRC from January 1990 to present.

The events in this report are classified into the following categories based on event reporting requirements defined by Title 10 of the Code of Federal Regulations (CFR):

- Lost/Abandoned/Stolen Material (LAS),
- Medical (MED),
- Radiation Overexposure (EXP),
- Release of Licensed Material or Contamination (RLM),
- Leaking Sealed Source (LKS),
- Equipment (EQP),
- Transportation (TRS), and
- Other (OTH).

A description of categories addressed in this report and associated screening criteria are presented in Appendix A.

1.2 NMED Data

A single occurrence report may be captured in more than one NMED event category. For example, a report may describe a loss of licensed material that also resulted in a radiation overexposure. In such a case, both event categories are recorded in NMED and identified by the same report number (referred to as an item number in the database).

The data presented in this report are limited to reportable events that occurred between October 1, 2011, and September 30, 2021. The data were downloaded from NMED on November 14, 2021. Because NMED is a dynamic database that is updated daily, variations in data may be encountered over time. Furthermore, even though many events were reported and entered in the database for operational experience purposes, only those events required to be reported by 10 CFR are addressed in this report.

This report displays annual trend data for each of the event categories for a 10-year period. A trend analysis was performed on each event category to identify the existence or absence of a statistically significant trend. If a statistically significant trend exists, the display indicates the direction and

approximate rate of change with a trend line. For the purposes of this report, a statistically significant trend exists if the analysis indicates that the computed fit and slope of a least squares linear model is valid at a 95% confidence level. A primer on the statistical methods employed in the trend analysis is presented in Appendix B.

Note that the trending methodology is not normalized; the trend only considers the number of reported events and does not directly account for external issues such as changes to regulatory requirements or changes in the number of licensees. For example, an increasing trend in the number of medical events could be caused by an increase in the number of medical procedures being performed. Likewise, an event type showing a decreasing trend for NRC licensees and an increasing trend for Agreement State licensees could be caused by States becoming Agreement States (resulting in fewer NRC licensees and more Agreement State licensees).

Reporting guidance for Agreement States is provided in the *Handbook on Nuclear Material Event Reporting in the Agreement States*. The handbook is an appendix to the NRC Office of Nuclear Material Safety and Safeguards procedure SA-300, *Reporting Material Events*. Access to NMED is available to the staff of NRC, Agreement State, and Federal agencies at http://nmed.inl.gov.

For assistance on searches or other questions, contact Robert Sun (nmednrc@nrc.gov, 301-415-3421).

2. ANALYSIS OF NMED DATA

Event reports submitted to the NRC involving nuclear material are reviewed, categorized, and entered into NMED. Charts are provided to display trends in annual data for the most recent 10-year period (FY11-20).

2.1 All NMED Events

Figure 1 displays the annual number and trend of NMED events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines).

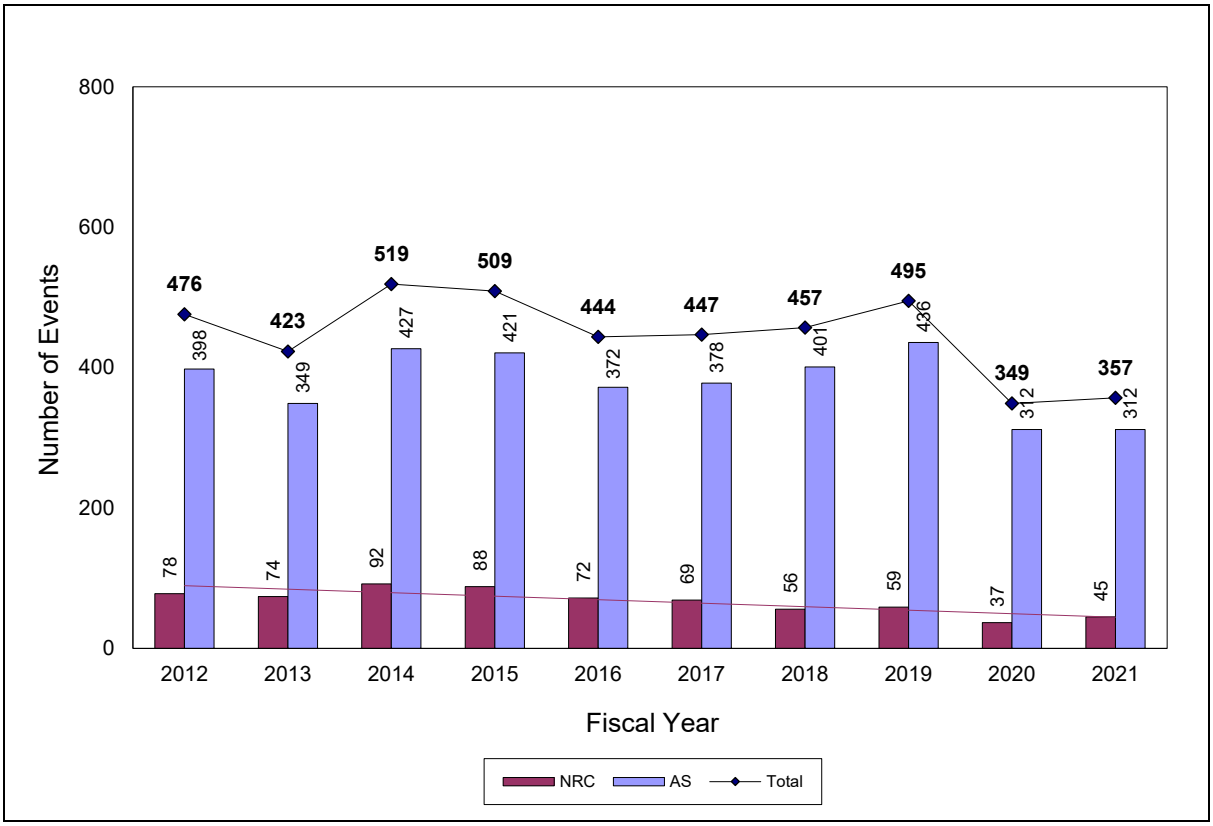

Figure 1. All NMED Events (4,476 total)

The following observations are made regarding the data in Figure 1.

- In FY21, 338 occurrences accounted for 357 events; a single occurrence can be classified in different event categories.
- The COVID-19 pandemic likely contributed to the decrease in events beginning in 2020.
- The most recent year's data are typically many records less than their final value when subsequent updates and late reports are received (see Appendix D, Figure D-1).
- The transition of states from NRC to Agreement State jurisdiction could result in increasing trends in Agreement State data and decreasing trends in NRC data.

Table 1 displays a summary of the trending analysis for all NMED event types included in this report. A more detailed discussion of the trending analysis results can be found in the section of this report devoted to each event type.

Table 1. Summary of Trending Analysis

Event Type	Total	NRC	Agreement State
All NMED Events	-	↘	-
Lost/Abandoned/Stolen Material (LAS)	-	↘	-
Medical (MED)	-	-	-
Radiation Overexposure (EXP)	↘	-	↘
Release of Licensed Material or Contamination (RLM)	-	-	-
Leaking Sealed Source (LKS)	-	-	-
Equipment (EQP)	-	-	-
Transportation (TRS)	↘	↘	-
Other (OTH)	NA	NA	NA

Notes:

- ↗ indicates a statistically significant increasing trend.
- ↘ indicates a statistically significant decreasing trend.
- - indicates no statically significant trend.
- NA indicates that the data does not support trending analysis.

2.2 Lost/Abandoned/Stolen Material

2.2.1 Ten-Year Data

Figure 2 displays the annual number and trend of LAS events that occurred during the 10-year period. The trend analysis determined that the NRC-regulated events represent a statistically significant decreasing trend (indicated by the trend line). However, the Total events and Agreement State-regulated events do not represent statistically significant trends (indicated by the absence of trend lines).

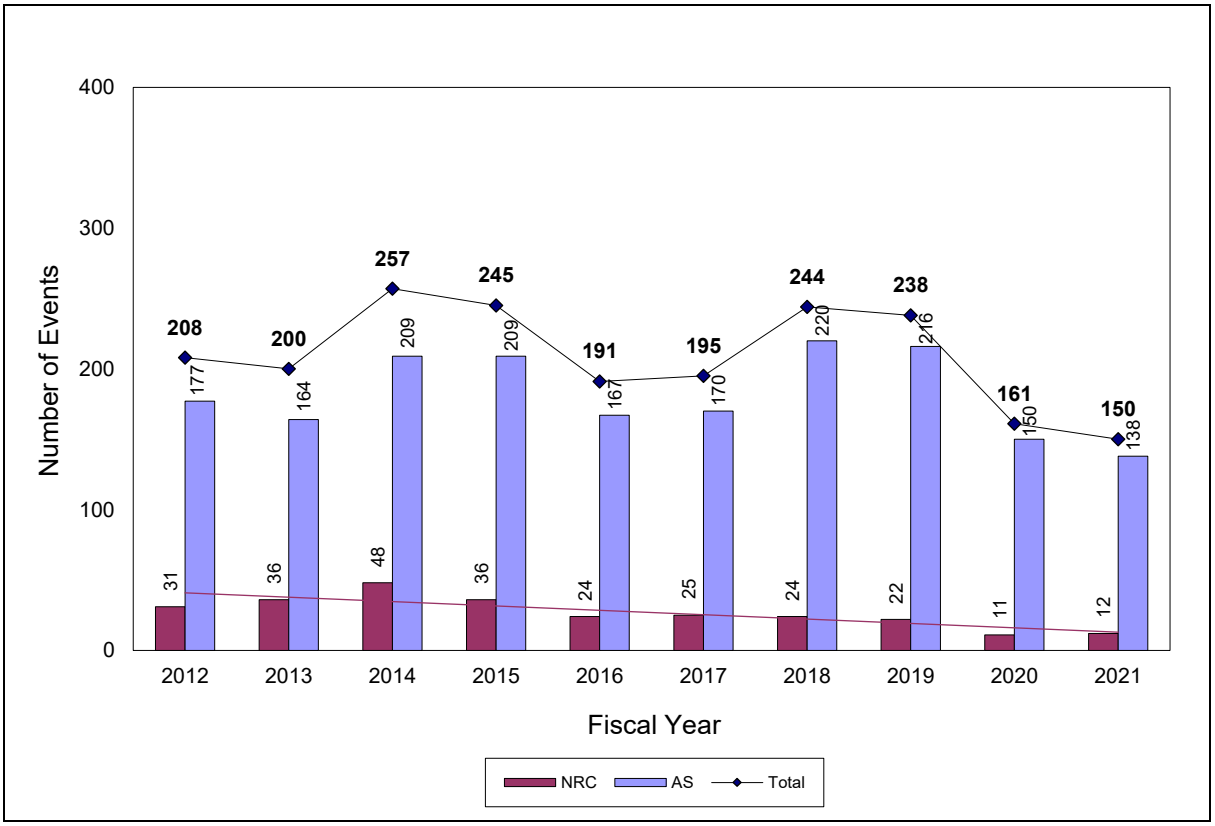

Figure 2. Lost/Abandoned/Stolen Material Events (2,089 total)

Appendix C contains a list of radionuclides derived from the International Atomic Energy Agency's (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources (2004)*. These radionuclides are grouped by the amount of radioactivity into five categories that correspond to the relative hazard, with Category 1 being the most hazardous.

For this report, IAEA Category 1 through 3 source events (excluding irretrievable well-logging source events) are considered significant. Regardless of IAEA category, events involving irretrievable well-logging sources are not considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 2 displays the number of sources lost (approximately 3,868, excluding irretrievable well-logging sources) during the 10-year period and the number that have not been recovered (approximately 2,264), grouped by IAEA category where possible. These included three Category 1 sources, 74 Category 2 sources, and 40 Category 3 sources; all of which were recovered, with the exception of one Category 2 and seven Category 3 sources.

Table 2. Number of Sources Lost/Abandoned/Stolen (LAS) and Sources Not Recovered (NR) - Excluding Irretrievable Well Logging Sources

Category		Fiscal Year 2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	Total
1	LAS[4]	0	0	0	2	0	0	0	0	1	0	**3**
	NR[5]	0	0	0	0	0	0	0	0	0	0	**0**
2	LAS	3	10	5	9	8	7	3	9	4	16	**74**
	NR	0	0	0	0	0	1	0	0	0	0	**1**
3	LAS	7	3	4	4	5	1	4	5	2	5	**40**
	NR	1	0	0	1	0	0	0	2	2	1	**7**
4	LAS	44	24	53	45	43	35	39	51	52	52	**438**
	NR	14	8	26	20	17	9	17	22	25	30	**188**
5	LAS	83	72	88	87	83	55	76	67	58	62	**731**
	NR	25	9	33	34	46	15	28	24	17	33	**264**
< 5	LAS	0	1	1	2	1	10	4	2	2	0	**23**
	NR	0	0	0	2	1	1	4	1	2	0	**11**
Activity Not Known[1]	LAS	9	7	3	3	1	1	3	4	17	2	**50**
	NR	0	0	0	1	0	0	0	1	0	0	**2**
Nuclide Not Known[2]	LAS	0	1	0	1	0	1	0	0	0	5	**8**
	NR	0	0	0	0	0	0	0	0	0	2	**2**
Other[3]	LAS	193	174	330	201	252	165	281	498	256	151	**2501**
	NR	132	92	257	110	187	75	173	398	227	138	**1789**
Total	**LAS**	**339**	**292**	**484**	**354**	**393**	**275**	**410**	**636**	**392**	**293**	**3868**
	NR	**172**	**109**	**316**	**168**	**251**	**101**	**222**	**448**	**273**	**204**	**2264**

Notes:

1. The “Activity Not Known” category includes sources containing radionuclides listed in Appendix C for which the activity was not reported. Therefore, the sources were not included in Categories 1 through 5.
2. The “Nuclide Not Known” category includes those sources for which the radionuclide was not reported. Thus, the sources were not included in Categories 1 through 5 or Other.
3. The “Other” category includes sources containing radionuclides not included in Appendix C.
4. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).

5. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The Category 1 through 3 “not recovered” source counts were corrected for the “partially recovered” source events.

Tables 3 and 4 provide more detail regarding the 10-year and current year “not-recovered” data highlighted in Table 2 in yellow and green, respectively. Table 3 displays radionuclide data pertaining to the IAEA Category 1 through 3 sources lost during the 10-year period that have not yet been recovered. The Decayed Activity values are conservative estimates in that the values are typically decayed from the loss date instead of the manufacturer’s assay date. As a result, the actual decayed activities (based on the manufacturer’s assay date) are likely less than the estimates. Table 4 is similar to Table 3 but limited to the current year.

Table 3. Summary of IAEA Category 1-3 Sources Not Recovered (FY12-21)

Radionuclide	Half-life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Total Decayed Activity IAEA Category
Ir-192	73.83 days	6	92.2	0.6	4
Pu-238	87.7 years	2	5.3	5.0	3
Total		**8**	**97.5**	**5.6**	**3**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the "partially recovered" source events.
4. The source activities were decayed from the event date to 11/14/2021 (data download date).

Table 4. Summary of IAEA Category 1-3 Sources Not Recovered (FY21)

Radionuclide	Half-life[1]	Number of Sources Not Recovered[2,3]	Total Activity (Ci)	Total Decayed Activity (Ci)[4]	Total Decayed Activity IAEA Category
Ir-192	73.83 days	1	10.6	0.6	4
Total		**1**	**10.6**	**0.6**	**4**

Notes:

1. Half-life values from the Chart of the Nuclides, 16th Edition.
2. Events involving a larger number of sources are sometimes entered as a single source with an aggregate activity (for example, the loss of a container of brachytherapy seeds may be entered as a single source with a total combined activity).
3. Events involving the loss/theft of multiple sources may involve the recovery of only some of the sources and are entered as being partially recovered (rather than marking each source individually). The source counts were corrected for the “partially recovered” source events.

4. The source activities were decayed from the event date to 11/14/2021 (data download date).

2.2.2 FY21 Data

One hundred fifty LAS events occurred in FY21, two of which involved irretrievable well logging sources. Excluding the irretrievable well logging sources, approximately 293 sources were lost/abandoned/stolen, 204 of which have not been recovered. Of the 293 lost sources, none were Category 1, sixteen were Category 2, and five were Category 3 sources; all of which were recovered except one Category 3 source.

Fourteen of the FY21 LAS events were considered significant (involved Category 1-3 sources). Note that regardless of IAEA category, events involving irretrievable well logging sources are not considered significant.

Significant Events - Category 1 Source Events
None

Significant Events - Category 2 Source Events
Item Number 200433 - A radiography equipment manufacturer reported that two radiography sources containing 2.41 and 1.22 TBq (65 and 33.1 Ci) of Ir-192 were lost during shipping. The sources were shipped (in a source changer) on 10/9/2020 to a customer in Great Britain. The common carrier reported that the package was missing on 10/22/2020. The carrier found the package at their hub in Memphis, Tennessee, on 10/23/2020. The package was returned to the manufacturer for inspection. No package damage, loss of contents, or change in package radiation levels were identified. The cause of the event was human error (misplaced package by carrier personnel). Corrective actions to prevent recurrence included carrier personnel retraining.

Item Number 200450 - A radiography services company reported that a radiography exposure device containing a 943.5 GBq (25.5 Ci) Ir-192 source was lost during shipping. The package was shipped from their Pennsylvania facility to their Oklahoma facility. The shipping paper arrived at the Oklahoma facility on 11/2/2020, but the package containing the device was missing. The company notified the common carrier. On 11/5/2020, the device was located by the carrier and scheduled to be delivered.

Item Number 210096 - A radiography equipment manufacturer reported that a radiography exposure device containing a 2.32 TBq (62.6 Ci) Co-60 source was lost during shipping. The package was shipped on 1/29/2021 to a customer in Canada. On 2/23/2021, the customer notified the manufacturer that the package had not arrived. The common carrier's records showed that the package was received at their facility in Memphis, Tennessee, on 1/31/2021, but there was no further tracking information. On 3/2/2021, the manufacturer reported that the missing package had been found at the carrier's facility in Memphis. The wooden crate containing the Type B package was damaged, but the Type B package was not damaged. The manufacturer sent materials to the carrier to repair the crate before the shipment continued to the customer.

Item Number 210098 - A radiography equipment manufacturer reported that a package containing seven Ir-192 sources in a source changer was lost during shipping. The sources contained activities of 2.22, 2.19, 2.15, 2.22, 2.20, 2.21, and 2.56 TBq (59.9, 59.2, 58.1, 59.9, 59.5, 59.8, and 69.2 Ci). The package was shipped on 2/12/2021 to a customer in Singapore. On 3/1/2021, the manufacturer discovered that the customer had not received the package. The common carrier indicated that the package's last known location was at their Memphis, Tennessee, facility on 2/13/2021. The manufacturer was notified on 3/5/2021 that the missing package had been located at the Memphis facility. The package was found undamaged and the shipment continued to Singapore.

Item Number 210133 - A radiography equipment manufacturer reported that a radiography exposure device containing a 3.89 TBq (105.2 Ci) Ir-192 source was lost during shipping. The package was shipped on 3/26/2021 to a customer in Corpus Christi, Texas. The package was last tracked by the common carrier in Memphis, Tennessee, on 3/30/2021, but there had been no movement recorded since

3/27/2021. The carrier initiated a trace of the package on 3/31/2021. The manufacturer was notified by the carrier on 4/6/2021 that the package had been delivered to its intended destination undamaged.

Item Number 210137 - A radiography equipment manufacturer reported that a radiography exposure device containing a 3.92 TBq (106 Ci) Ir-192 source was lost during shipping. The package was shipped on 4/1/2021 from Baton Rouge, Louisiana, to a customer in Farmington, New Mexico. The package arrived at the common carrier's facility in Memphis, Tennessee, on 4/1/2021. The package was subsequently delivered to the customer on 4/7/2021.

Item Number 210183 - A radiography services company reported that a radiography exposure device containing a 3.89 TBq (105 Ci) Ir-192 source was lost during shipping. The package was shipped on 4/29/2021 from a radioactive equipment manufacturer in St. Rose, Louisiana. The common carrier delivered the package to the radiography services company (in Romeoville, Illinois) on 4/30/2021. However, the cardboard overpack was damaged and the box was empty. There was suspicion that the device/source were lost in the carrier's Memphis, Tennessee, hub. The Tennessee Department of Environment & Conservation was alerted and reached out to the carrier. Illinois Emergency Management Agency inspectors arrived at the carrier's Hillside, Illinois, facility to further investigate. The package was marked as damaged when it arrived at the carrier's Hillside facility immediately prior to delivery. The carrier contacted the company on 5/4/2021 to report that the device/source had been located at their Memphis hub. The radiography services company picked up the device/source on 5/4/2021 and confirmed that there was no damage. No radiation exposures were anticipated from the event and all security seals were intact.

Item Number 210305 - A radiography services company reported a temporary loss of control of a radiography exposure device that contained a 3 TBq (81 Ci) Ir-192 source. The company's Director of Radiation Safety was notified by a radiographer working in Prudhoe Bay, Alaska, that the exposure device had been left unsecured in a truck in an ammo can with no lock and without the alarm set. The truck had been left at a shop for maintenance. At approximately 0200 on 7/29/2021, maintenance shop personnel discovered the device in the truck. They immediately closed the truck and notified security. They did not handle the device. The exposure device was retrieved by the radiography services company. The location of the event in Prudhoe Bay was a secure location with no access without proper security clearance.

Item Number 210313 - A radiography services company reported that a 2.394 TBq (64.7 Ci) Ir-192 source was lost in shipping. The package was shipped on 7/12/2021 from their facility in Strasburg, Ohio, to their facility in Michigan. The common carrier was contacted and believed that the package was delayed at their facility in Memphis, Tennessee. The carrier informed the company on 7/20/2021 that the package could not be located. The State of Tennessee was informed. The company reported on 7/23/2021 that the source had been located at the carrier's facility in Canton, Ohio. Contrary to an earlier report, the source was never transported to the carrier's Memphis facility. The company retrieved the source from the Canton facility.

Significant Events - Category 3 Source Events

Item Number 200485 - A radioactive source vendor reported that a high dose rate source containing 423.28 GBq (11.44 Ci) of Ir-192 was lost during shipping. The source was shipped on 11/13/2020 from Vinton, Louisiana, to a medical center in Palo Alto, California. The source was last tracked in the common carrier's Memphis, Tennessee, hub on 11/14/2020. The source was subsequently located.

Item Number 210043 - A radioactive source vendor reported that a high dose rate source containing 391.02 GBq (10.568 Ci) of Ir-192 was lost during shipping. The vendor's RSO dropped the source off at a common carrier in Lake Charles, Louisiana, on 1/5/2021, for shipment to a medical center in The Dalles, Oregon. The carrier's Memphis, Tennessee, hub did not show this source being tracked or received. The cause of the event was that the carrier's shipping computer was down at the time of delivery. The source was left with the carrier, but not entered into the receiving system; it was understood

that the source would be entered into the system once the system was back online. A total of 18 sources were dropped off, but one was not entered into the tracking system, which ended up being the one lost. In the future, the vendor will get a signed receipt from the carrier for sources dropped off or picked up.

Item Number 210142 - A radiography services company reported that a radiography exposure device containing a 1.09 TBq (29.4 Ci) Se-75 source was lost during shipping. The package was shipped on 4/5/2021 from Neenah, Wisconsin, to the company's facility in Kingsport, Tennessee. The package was shipped overnight with the intent to be delivered on 4/6/2021. The common carrier reported that the package was delayed at their Memphis, Tennessee, facility. The package arrived at the Kingsport facility on 4/8/2021, damaged and without the device. The company contacted the common carrier and the source manufacturer to locate the device. The Wisconsin Department of Health Services monitored efforts to locate the device and coordinate with other jurisdictions as necessary. The carrier determined that the package contents must be within their Memphis facility. The entry weight on the package at that facility was recorded as 54 pounds and the exit weight leaving that facility was 3 pounds. The device was located on 4/15/2021 and the company was notified to come retrieve the contents.

Item Number 210238 - A radioactive source services company reported that a package containing 925 GBq (25 Ci) of Cs-137 was lost during shipping. The package was shipped from Wisconsin on 4/16/2021 but did not arrive at its destination in California. The last known location of the package was in Chicago, Illinois, on 4/22/2021. The package eventually arrived at its destination on 6/7/2021. The package was completely intact, including the seal, with no signs of damage. When the company contacted the common carrier, they were not provided with any details of problems during shipment. However, the package was located and promptly delivered.

Item Number 210255 - A boiler manufacturer reported that a 307.1 GBq (8.3 Ci) Ir-192 source was lost during shipping. The source was shipped in a source changer on 5/19/2021 to the source manufacturer in in Burlington, Massachusetts. When the boiler manufacturer did not receive a confirmation of receipt, they contacted the common carrier on 6/14/2021 who confirmed that the package was lost. The carrier found the package on 6/21/2021 in Durham, North Carolina. It had been delivered to an incorrect shipping warehouse. The error was discovered by reviewing video footage and noticing the package being loaded onto a truck bound for Durham. The carrier retrieved the package and delivered it to the source manufacturer (receipt confirmation on 6/25/2021).

Events of Interest
None

2.2.3 Events Recently Added to NMED That Occurred Prior to FY21

Eighteen LAS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Category 1 Source Events
None

Significant Events - Category 2 Source Events
None

Significant Events - Category 3 Source Events
None

Events of Interest
None

2.3 Medical

2.3.1 Ten-Year Data

Figure 3 displays the annual number and trend of MED events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

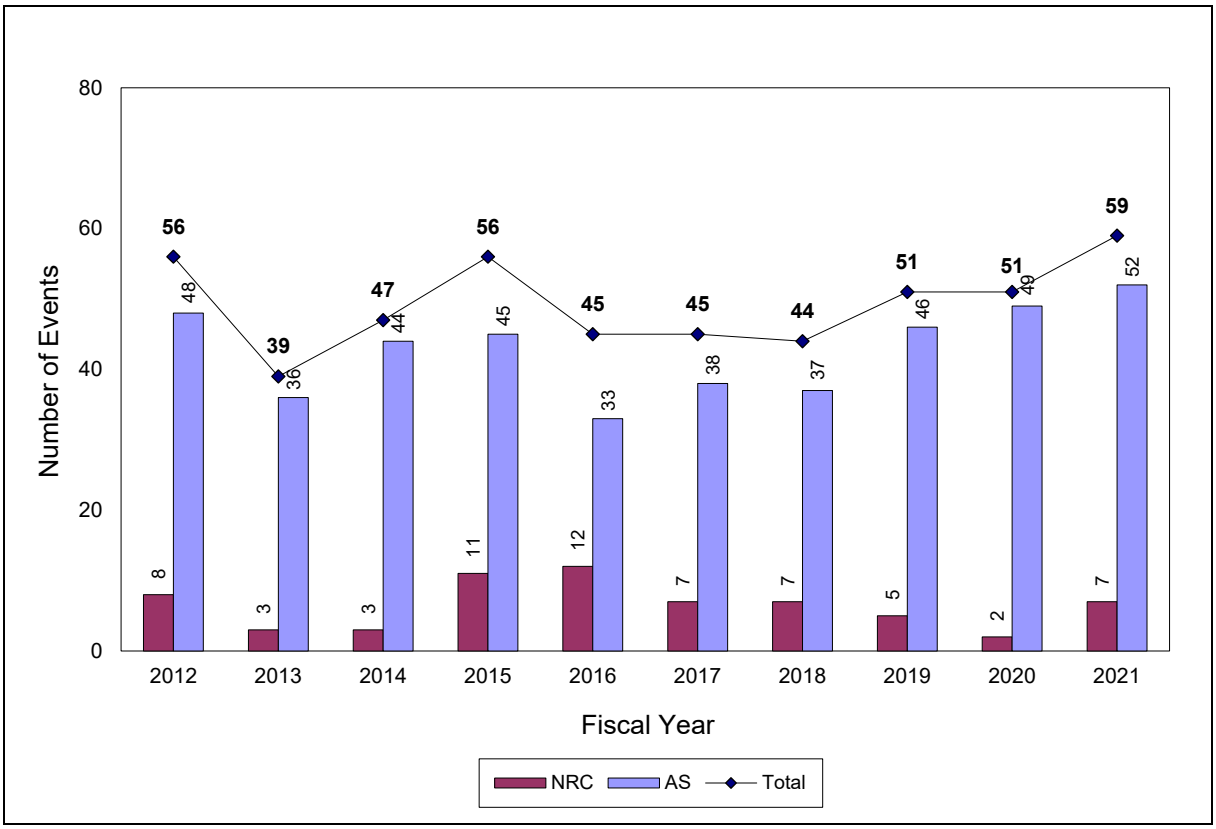

Figure 3. Medical Events (493 total)

Table 5 lists the number of MED events that were classified as Abnormal Occurrences (AOs) in NUREG-0090, *Report to Congress on Abnormal Occurrences*. Note that recent events are considered potential AOs until they complete NRC's formal AO determination process and are reported in NUREG-0090. Potential AO events are included in Table 5. Also included are events involving doses to an embryo/fetus or a nursing child (reportable per 10 CFR 35.3047). By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as an "Other" event. However, they are included here for reference.

Table 5. Medical and Embryo/Fetus or Nursing Child - AOs or Potential AOs

	Fiscal Year										
	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Medical	13	7	11	14	7	10	8	7	8	7	**92**
Embryo	1	2	1	1	1	0	0	0	1	1	**8**
Total	**14**	**9**	**12**	**15**	**8**	**10**	**8**	**7**	**9**	**8**	**100**

For this report, events classified as AOs (or potential AOs) are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.3.2 FY21 Data

Fifty-nine MED events occurred in FY21, seven of which were considered significant and classified as potential AOs.

Significant Events - AOs or Potential AOs

Item Number 200424 - A patient received more dose than prescribed during a Y-90 microsphere treatment on 10/16/2020. The patient was prescribed to receive a different microsphere dose to two different lobes of the liver. The physician mistakenly delivered the larger activity to the left lobe, which should have received the smaller activity. The patient was prescribed 489.14 MBq (13.22 mCi) for a dose of 7,000 cGy (rad) to the left lobe. However, 1,168.09 MBq (31.57 mCi) was administered to the left lobe, for a dose of 17,500 cGy (rad). The error was discovered after the left lobe was treated. The right lobe was treated correctly with approximately 1,168.09 MBq (31.57 mCi). The California Health and Human Services Agency investigated the incident. The event occurred due to an error in labeling the two dosage containers and a failure to compare the dosage to the written directive. While each container brought to the authorized user (AU) was mislabeled with the intended target location, all other information was correct. Corrective actions included a revised procedure that specifies that the only labeling allowed on Y-90 microsphere containers will be the patient's initials, radionuclide, activity, and date. A description of the target/treatment site will not be included on the container. Additionally, a time-out was incorporated in the procedure for the AU and health physicist to compare each dose to the written directive to ensure they are identical. Following review of the written directive, it will be signed by the AU.

Item Number 210007 - A patient was erroneously administered a therapeutic dose of I-131 instead of the intended diagnostic dose of I-123 on 12/15/2020. Due to miscommunication between the scheduling and nuclear medicine departments, the written directive incorrectly prescribed an I-131 ablation treatment. The patient should have received μCi amounts of I-123 but was administered 584.6 MBq (15.8 mCi) of I-131. The dose to the patient was estimated to be 34,000 cSv (rem) to the thyroid, 1,360 cSv (rem) effective dose equivalent, and 4.2 cSv (rem) shallow dose equivalent. The patient’s thyroid was ablated. The patient was notified of this event on 12/28/2020. The root cause of this event was the absence of a standardized workflow methodology between the scheduling and nuclear medicine departments, combined with the absence of a description of duties and responsibilities for each worker. Corrective actions included procedure modification to require that, after obtaining a request from the clinical service, the authorized user review the patient’s clinical situation to determine if the particular treatment option is appropriate. Other process improvements were also implemented.

Item Number 210155 - A patient was administered a therapeutic dose of I-131 instead of the intended diagnostic dose of I-123 on 4/14/2021. The patient was prescribed to receive 7.4 MBq (200 μCi) of I-123 as a thyroid diagnostic procedure, but instead received 5.55 GBq (150 mCi) of I-131. The error was quickly realized and the patient was called and asked to return to the hospital. The patient stated that she did not vomit or use a bathroom before returning to the hospital. The patient was given potassium iodide and stayed at the hospital for four days under I-131 administration safety protocols. The hospital consulted with the Radiation Emergency Assistance Center/Training Site (REAC/TS) and confirmed their course of treatment. The patient indicated that she would stay at home for a week before returning to work. The planned dose to the patient's thyroid was 2.37 cGy (rad). An early estimate of the dose received ranged from 1,220 cGy (rad) for a blocked thyroid to 155,000 cGy (rad) for a low thyroid uptake. The estimate could not accurately account for the potassium iodide administration. The hospital reported on 6/11/2021 that the patient had lost her sense of taste and was on Synthroid medication. The cause was determined to be repeated errors by the nuclear medicine technologist (NMT). The appearance and size of I-123 and I-131 capsules are very different; I-123 capsules are orange and blue, while I-131 capsules are

white. The containers for both capsules are also very different. Therapeutic doses are kept in a separate room as a safety precaution. The patient's name and date-of-birth is visible on the outside labels for both diagnostic and therapeutic doses. In addition, capsules are measured in a dose calibrator to ensure correct dosage. All iodine procedures will now require that two NMTs sign-off before administration. An NMT's initial competency will be evaluated between diagnostic and therapeutic doses to determine if revision and clarity would be beneficial. The involved NMT's employment was terminated. A Safety Event Analysis was scheduled to review the incident with members from Patient Safety, Nuclear Medicine, Radiology, and Risk Management.

Item Number 210200 - A patient received a dose to the wrong location during a Y-90 microsphere treatment on 5/10/2021. The patient was prescribed to receive a dose of 2.55 GBq (68.92 mCi) to the left lobe of the liver for a dose of 13,000 cGy (rad). However, post-treatment imaging on 5/11/2021 identified that the dose was delivered to the right lobe; 2.48 GBq (66.96 mCi) for a dose of 12,700 cGy (rad). The referring physician and patient were notified. The Ohio Department of Health conducted an investigation on 6/3/2021. No definitive cause was identified for the incident. The catheter placement was verified by angiography and fluoroscopy just prior to treatment and was locked in place to prevent movement. The hospital believed the catheter "kicked out" during treatment. Corrective actions included a new written procedure. The patient had previously received treatment to the right lobe of the liver. The hospital estimated the total dose to the right lobe was 20,000 cGy (rad) and did not expect any adverse effects to occur.

Item Number 210209 - During a prostate brachytherapy procedure on 5/10/2021, most of the Cs-131 seeds were inadvertently implanted into the perineum below the prostate. The error was discovered during a review of the post-treatment CT exam on 5/12/2021. The treatment plan was to place stranded seeds around the prostate periphery and individual seeds at the apex, base, and interior of the prostate. However, prior to placing the stranded seeds, the ultrasound probe was not adequately advanced on sagittal imaging to visualize the prostate gland. As a result, the stranded brachytherapy seeds were placed immediately below the prostate extending into the perineum. In total, 63 of 78 stranded seeds were implanted in the perineum and 15 loose seeds were implanted in the prostate. The prostate D90 dose was only 26.26% of the prescribed dose. The written directive prescribed an activity of 7.34 GBq (198.26 mCi), but the patient only received 1.41 GBq (38.12 mCi) to the prostate. The perineal region received a V100 dose of 11,500 cGy (rad). The urethra and rectum received significantly less dose than intended, approximately half. The prescribing physician was informed and notified the patient on 5/13/2021. The hospital implemented corrective actions. Prior to implant procedures, a frame of reference will be established using the stepper position to identify the base and apex of the prostate on axial and sagittal planes. During implant procedures, a timeout will be performed to verify the location of the prostate and bladder. A retraining program of the prostate seed program was planned to include, but not be limited to, retraining and proctoring by a qualified radiation oncology physician and physicist. The patient did not experience any acute symptoms. The patient received external beam radiation therapy to boost treatment to the areas of the prostate that did not receive the prescribed dose. The patient was scheduled for long term follow-up to track his prognosis and any complications.

Item Number 210258 - A Y-90 microsphere (Sirtex Medical model SIR-Spheres) treatment intended for the left lobe of a patient's liver was inadvertently administered to the left and right lobes. The treatment plan prescribed between 0.29 and 0.83 GBq (7.84 and 22.43 mCi) to the left lobe. The reason for the activity range was that if the lobe became saturated, the treatment would be stopped. During the treatment, periodic flushing cycles with contrast and fluoroscopy were performed. Mid-way into the administration, the team discovered contrast material in the right lobe, indicating that the microcatheter had moved. The procedure was stopped and the microcatheter was replaced with a new microcatheter. The remaining microspheres were then infused to the left lobe without incident. A post-treatment Bremsstrahlung image confirmed that both lobes received Y-90 activity. The radiation oncologist estimated that the left lobe received less than the prescribed activity. The right lobe received between

33% and 67% of the Y-90 activity. Treatment to the right lobe was not intended (the patient had been treated with microspheres to the right lobe on 6/1/2021). The dosimetry information included in the package insert shows that if 75% of the activity was delivered to the right lobe, the estimated dose would be approximately 2,000 cGy (rad). Additionally, if only 25% of the activity was delivered to the left lobe, it would have been underdosed by about 33%. The patient was informed of the incident. According to the treating radiation oncologist, the microcatheter needed to be close to the branching point between the left and right arteries in order to ensure that some of the microspheres were infused down the small side-branch of the left artery. They suspect that with respiratory motion and vascular pulsations, there was sufficient movement to cause the microcatheter to move to the right artery near the branching point. The microcatheter was confirmed to be correctly placed with fluoroscopy before initiation of the treatment. The fluoroscope was not continuously run during the procedure but was used during each flushing cycle. The treating physicians did not anticipate any adverse effect and there was a potential beneficial effect from the additional dose to the tumors in the right lobe. The patient was scheduled for continued evaluation and will receive a second dose to the left lobe if medically indicated. There were no corrective actions planned.

Item Number 210352 - During a prostate brachytherapy procedure on 7/26/2021, all of the I-125 seeds were inadvertently implanted in the penile bulb instead of the prostate. The treatment plan was to implant 54 I-125 seeds with a total activity of 1.013 GBq (27.378 mCi) in the prostate for a prescribed dose of 14,500 cGy (rad). On 8/17/2021, the patient's follow-up CT scan revealed that all 54 seeds were implanted in the patient's penile bulb, outside of the intended target. The patient and physician were notified. A North Carolina Department of Health and Human Services inspector was dispatched on 8/18/2021. Through interviews with the medical physicist, the RSO, and the chief physicist, a malfunction of the ultrasound unit was ruled out. The physicist's retrospective review indicated that if the Foley catheter was not clearly visible on the ultrasound images, then it could result in seed implantation in a location other than the prostate. A dose to the penile bulb of approximately 14,500 cGy (rad) was received, where no dose was anticipated. The preliminary cause was human error. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure that personnel clearly identify the prostate gland and the surrounding anatomy.

Events of Interest

Item Number 210182 - A patient received a dose to an unintended site during a gynecological treatment on 4/28/2021. The treatment involved a high dose rate afterloader unit and a 256.41 GBq (6.93 Ci) Ir-192 source. The patient was prescribed five fractions of 600 cGy (rad) each, to be delivered every other day. After the third fraction was complete, it was determined that a 125 cm transfer tube (green connector tube) was inadvertently used instead of a 113 cm transfer tube (black connector tube). Therefore, the radiation dose was deposited 12 cm away from the intended treatment site. The authorized medical physicist notified the authorized user and management. The patient was notified on 4/29/2021. The confusion in the transfer tube arose from the fact that there were two tube lengths available for use and the authorized medical physicist did not identify the incorrect tube length during the verification process. The authorized user and prescribing physician reviewed event details and confirmed that no harm to the patient was expected. The department initiated immediate corrective actions. The chief physicist removed all transfer tubes from the treatment room and all future treatments will only use the 125 cm tubes. The removal of the transfer tubes will ensure only one option is available for treatment planning. All physicists were reminded of the mandatory checks before starting treatment to re-educate all physicists of the procedural process for the quality assurance verification. On 5/25/2021, the hospital confirmed that the vaginal cuff did not receive any exposure during the event. The exposure was delivered 12 cm short of the intended treatment site. That tissue is largely comprised of fatty tissue. The maximum dose to any tissue was 600 cGy (rad).

Item Number 210192 - A patient received a dose to an unintended site during a gynecological treatment on 5/4/2021. The treatment involved a high dose rate afterloader unit and a 190.04 GBq (5.13613 Ci) Ir-

192 source. The source transfer tube was approximately 12 cm too long. The maximum shallow dose received was 800 to 900 cGy (rad) to the vagina. The patient was notified. No adverse health effects were expected. The root cause was failure of medical staff to follow established procedures and identify a difference in the planned transfer tube length and the measured transfer tube length. The hospital added expected lengths of different channels in the pre-treatment delivery checklist, which will highlight the need to reconcile the measured vs. expected length. They also added the measured length with the source position check ruler for each channel. The physicist will approve the checklist prior to treatment to allow for enough time for the physician to verify the accuracy of all parameters for the intended treatment.

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs

Doses to an embryo/fetus or nursing child are reportable per 10 CFR 35.3047. By definition, these events are not medical events (reportable per 10 CFR 35.3045) and are captured in NMED as "Other" events. However, it is appropriate to also discuss these events in this section. One of these events occurred in FY21.

Item Number 210467 - An embryo/fetus received a radiation dose when a patient who was unknowingly pregnant (or became pregnant shortly afterwards) was administered a radiotherapy treatment of 5.48 GBq (148 mCi) of I-131 on 9/30/2021. The patient received a negative pregnancy test prior to the treatment. At a later date, the patient realized that she was pregnant and estimated the date of conception to be either 9/29/2021 or 10/10/2021. The RSO estimated the dose to the embryo/fetus to be 394 mSv (39.4 rem) based on a conception date of 9/29/2021. The estimated dose to the embryo/fetus would be 1.7 mSv (0.17 rem) based on a conception date of 10/10/2021.

2.3.3 Events Recently Added to NMED That Occurred Prior to FY21

Six MED events and no embryo/fetal dose events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of the MED events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - AOs or Potential AOs

None

Events of Interest

Item Number 200257 - A cancer center reported a medical event that involved a high dose rate unit cervix treatment using a tandem and ring with a 192.07 GBq (5.191 Ci) Ir-192 source. After the treatment was completed and the device removed from the patient, it was discovered that the tandem had broken into two pieces. It was unknown where the source was positioned during the treatment. No warnings or errors from the machine were recorded from either the check source or the treatment cable. The source was in the patient for a total of 564.7 seconds. Of that time, the source was in the tandem for a total of 355.2 seconds. The physician and patient were notified of the event. It was determined that the break in the tandem occurred about four inches from the end of the tandem, at the beginning of the bend on the insertion end at the start of the ring. Using the location of the guide wire, it appeared that the source tracked next to the tandem and that the exposure occurred only to the intended tissue. The patient was to receive a total of 2,750 cGy (rad) in five fractions of 550 cGy (rad) each. The patient was receiving the third fraction when the event occurred. The cancer center stated that there was no way to know with certainty where the source was during the time of treatment but believed that the most probable path would have been the same as the markers, which was determined to have traveled along the tandem within 2 mm lateral of the intended position, resulting in minimal dose difference to the intended tissue. If the source did not travel along the tandem after the break, the dose to other possible tissue would have ranged from 450 to 600 cGy (rad). The cancer center stated that had the wire stuck at the cervix, it would have likely caused a fault on the machine because the drive wire for the source is stiffer than the wire for the markers. The final 2 cm of insertion of the marker wire had a small resistance but did not prevent the

wire from being fully inserted on a second attempt. The markers were removed prior to treatment and no fluid or abnormalities were observed on the wire. The transverse plane on the CT was not checked inferior of the ring until the device was removed from the patient, which revealed that the markers were outside of the applicator. A contamination survey of the source wire was completed and no contamination was detected. After a comprehensive internal review by the Radiation Oncology Quality Committee with physician and physics leadership, it was determined that the remaining two fractions would be completed. The tandem was first used in March 2019 and was used a total of 53 times prior to this event. The cancer center purchased new, thicker tandems to use in the future. They also modified their procedure to require that all views of the markers be reviewed prior to treatment. They will periodically x-ray the tandems to make sure there are no flaws. The manufacturer investigated the incident but did not identify a root cause. There were no indications that this incident was a trend. All devices can continue to be used as intended. The manufacturer believed that the surface breakage was influenced by the bending process of the tandem during manufacturing and the subsequent forces applied during repeat insertions and sterilizations. Based upon their records, they had seen similar breaks in 0.4% of all bend-manufactured parts (the white plastic material portion of the applicator where the break occurred). Based upon data, no modifications were planned for the tandem. However, the manufacturer evaluated a new method of manufacturing (bending of material), which was expected to reduce the risk of tandem break failure. This event was classified as an EQP and MED event.

Embryo/Fetus or Nursing Child Dose Events - AOs or Potential AOs
None

2.4 Radiation Overexposure

2.4.1 Ten-Year Data

Figure 4 displays the annual number and trend of EXP events that occurred during the 10-year period. The trend analysis determined that the Agreement State-regulated and Total events represent statistically significant decreasing trends (indicated by the trend lines). However, the NRC-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line).

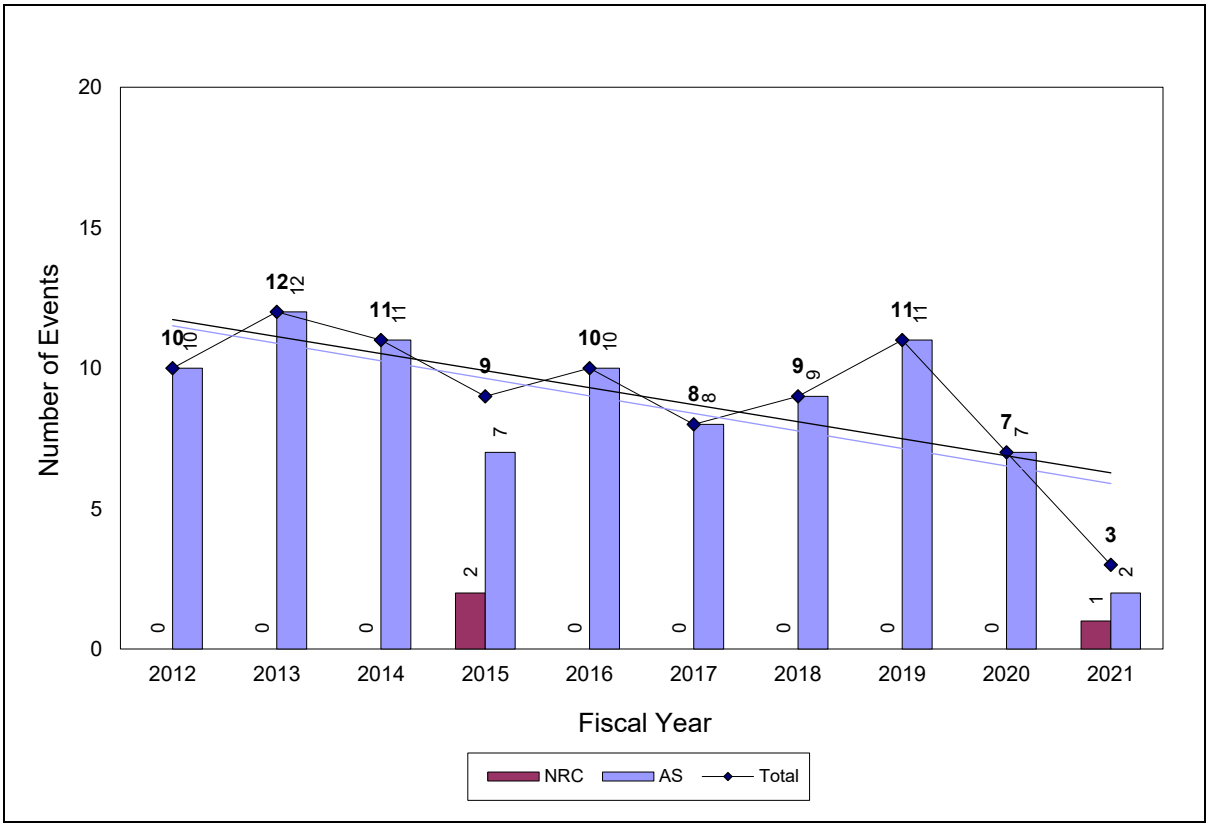

Figure 4. Radiation Overexposure Events (90 total)

The significance of individual EXP events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate or 24-hour reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 6 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 6. EXP Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Immediate	1	0	0	0	1	0	1	0	0	0	**3**
24-Hour	4	1	3	4	1	2	3	4	0	0	**22**
30-Day	5	11	8	5	8	6	5	7	7	3	**65**
Total	**10**	**12**	**11**	**9**	**10**	**8**	**9**	**11**	**7**	**3**	**90**

2.4.2 FY21 Data

Three EXP events occurred in FY21, none of which were considered significant.

Significant Events - Immediate Reporting
None

Significant Events - Within 24-Hour Reporting
None

Events of Interest
None

2.4.3 Events Recently Added to NMED That Occurred Prior to FY21

Two EXP event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Neither of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting
None

Significant Events - Within 24-Hour Reporting
None

Events of Interest
None

2.5 Release of Licensed Material or Contamination

2.5.1 Ten-Year Data

Figure 5 displays the annual number and trend of RLM events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

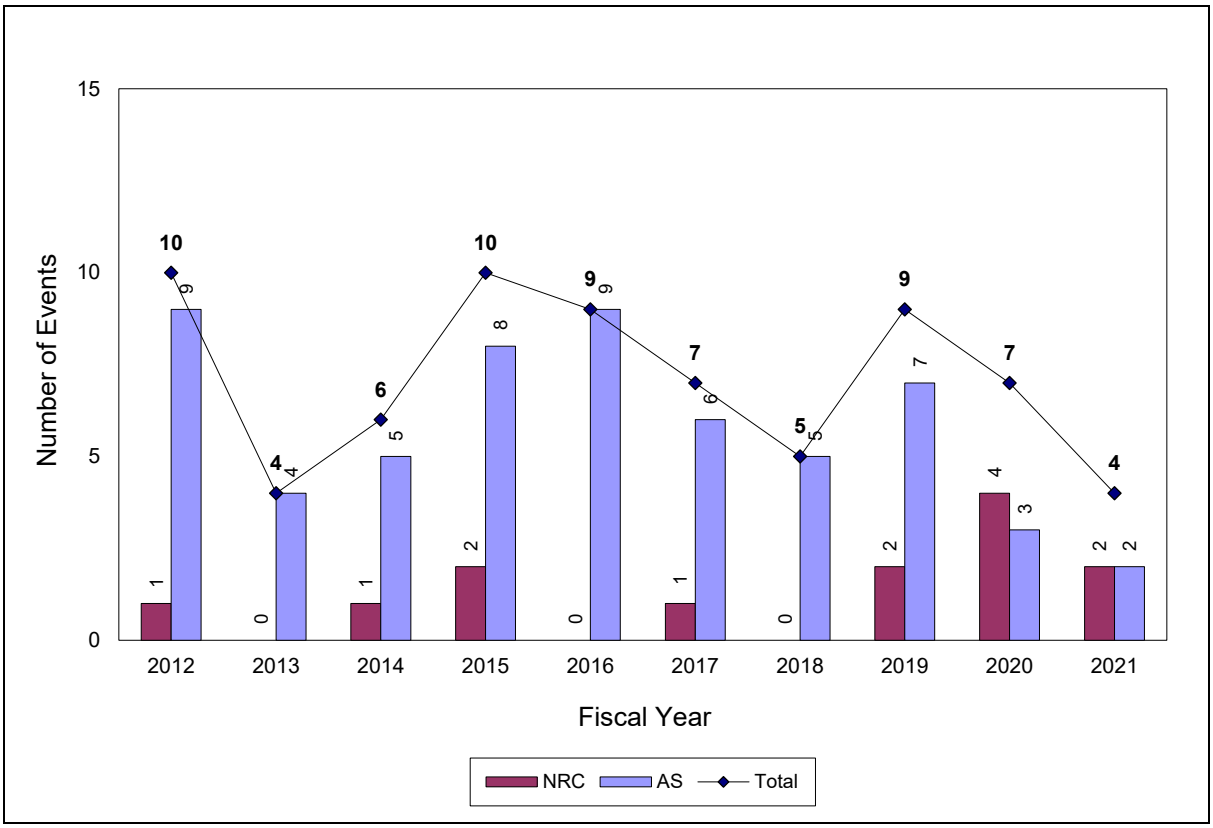

Figure 5. Release of Licensed Material or Contamination Events (71 total)

The significance of individual RLM events may be determined by the CFR reporting requirement applicable to the event. For example, an event that is required to be immediately reported is typically more significant than an event with a 30-day reporting requirement. For this report, events requiring immediate reporting are considered significant. Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

Table 7 displays the number of events based on the different reporting requirement time categories. Note that each event is counted only once. If an event involved exposures that were reportable in more than one category, the event is counted in only the most restrictive category.

Table 7. RLM Events Classified by CFR Reporting Requirement

	Fiscal Year										
	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**Total**
Immediate	2	1	1	1	1	3	1	1	1	0	**12**
24-Hour	6	2	3	9	8	3	4	6	5	3	**49**
30-Day	2	1	2	0	0	1	0	2	1	1	**10**
Total	**10**	**4**	**6**	**10**	**9**	**7**	**5**	**9**	**7**	**4**	**71**

2.5.2 FY21 Data

Four RLM events occurred in FY21, none of which were considered significant.

Significant Events - Immediate Reporting
None

Events of Interest
None

2.5.3 Events Recently Added to NMED That Occurred Prior to FY21

Five RLM events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. These events were not considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events - Immediate Reporting
None

Events of Interest
None

2.6 Leaking Sealed Sources

2.6.1 Ten-Year Data

Figure 6 displays the annual number and trend of LKS events that occurred during the 10-year period. The trend analysis determined that the data do not represent statistically significant trends (indicated by the absence of trend lines).

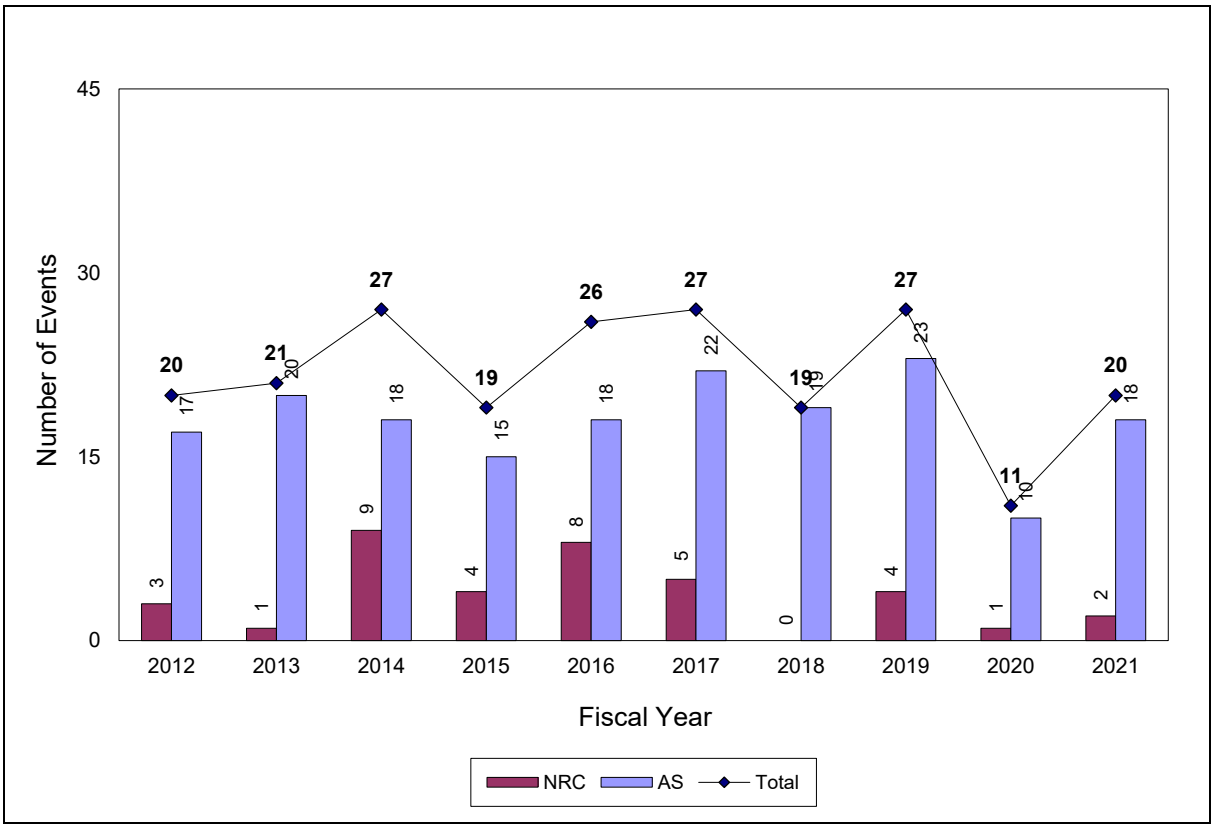

Figure 6. Leaking Sealed Source Events (217 total)

It is not possible to discern the significance of LKS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). There are essentially no immediate or 24-hour reporting requirements for leaking sources. The exception is 10 CFR 39.77(a), which is an immediate report to the NRC Regional office of a ruptured well logging source. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.6.2 FY21 Data

Twenty LKS events occurred in FY21, none of which were considered significant.

Significant Events
None

Events of Interest
None

2.6.3 Events Recently Added to NMED That Occurred Prior to FY21

One LKS event was recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. This event was not considered significant. Note that this data

may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
None

2.7 Equipment

2.7.1 Ten-Year Data

Figure 7 displays the annual number and trend of EQP events that occurred during the 10-year period. The trend analysis determined that the data does not represent statistically significant trends in the number of events (indicated by the absence of trend lines).

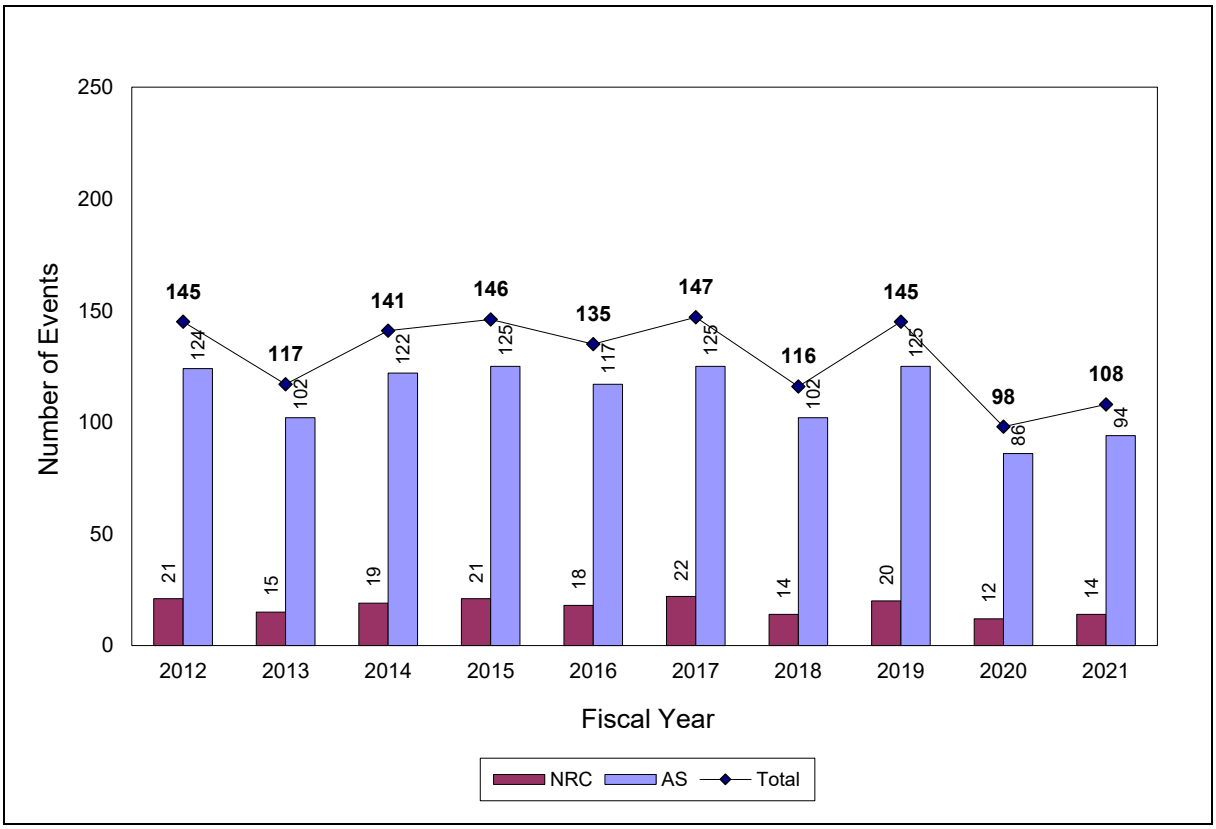

Figure 7. Equipment Events (1,298 total)

It is not possible to discern the significance of EQP events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5) because essentially all of the CFRs associated with EQP events require reporting within 24-hours. Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.7.2 FY21 Data

One hundred eight EQP events occurred in FY21, none of which were considered significant.

Significant Events
None

Events of Interest
Item Number 200417 - A radiopharmaceutical manufacturing company reported that an explosive chemical reaction occurred on 10/20/2020 that resulted in the loss of integrity of the hot cell. Staff were working with more than 37 GBq (1 Ci) of Sr-82 and Sr-85 inside the hot cell. The pressure from the explosion forced open the back door to the hot cell and damaged its latch. The chemist operating the hot cell activated the fire suppression system to fill the hot cell with argon gas and extinguish the fire. The

chemist then closed the hot cell door, turned off equipment to stop the manufacturing process, and evacuated the area. The RSO immediately restricted access to the area. Surveys, ventilation monitors, area radiation monitors, and bioassays confirmed that no radioactive material was released; the Sr-82 remained stable in a glass vessel. A reconstruction of the event determined that a spark from a frayed electrical connection caused explosive vapors from an uncapped bottle of cleaning solution to explode. The door latch and electrical connections were repaired. To prevent recurrence, argon gas will be used to provide a nonreactive atmosphere throughout the manufacturing process, cleaning solutions and all combustible material will be removed from the hot cell during production, and a preventive maintenance program will be established for the hot cells. A similar event occurred at this facility five months earlier (see Item Number 200225).

Item Number 200481 - A panoramic irradiator facility reported that the east pool irradiator source rack became stuck in the unshielded position on 11/30/2020. The source rack contained approximately 48.1 PBq (1,300,000 Ci) of Co-60 sources. The incident occurred in the middle of performing scheduled routine safety checks. The west source rack lowered as designed without incident. The RSO was contacted and immediately responded to the site to assist in assessment and formulation of an action plan. After consulting with the corporate RSO, a hand winch was used to successfully lower the rack into the shielded position within the pool. The east source rack was unshielded for approximately three hours. No radiation exposure occurred to personnel or members of the public. Safety and security systems remained operational and functioned as designed throughout the source lowering process. On the morning of 12/1/2020, the source modules were removed from the east source rack and shielded in safe storage at the bottom of the pool. The empty source rack was raised for inspection using a hand winch. A worn guide tube was discovered. Appropriate repairs were performed on 12/2/2020. As of 12/4/2020, both source racks had been reloaded and tested satisfactorily.

Item Number 200483 - A construction materials testing company reported that a moisture/density gauge was damaged at a construction site in Seattle, Washington, on 11/30/2020. The gauge contained a 1.85 GBq (50 mCi) Am-Be source and a 0.37 GBq (10 mCi) Cs-137 source. The Cs-137 source was extended when a mini-dozer ran over the gauge. The handle used to extend and retract the Cs-137 source rod broke off from the gauge completely. That led to a concern that the source had broken off the rod. Personnel on site were evacuated and the area secured. A company licensed to repair these gauges responded to the scene to recover the unshielded source. They determined that the source had not detached from the rod. A leak test to check the integrity of the source revealed no leakage and the source rod was retracted back into the gauge. Radiation surveys of the area were conducted to ensure that there were no remaining safety concerns. The damaged gauge was taken to the gauge-repair facility and secured pending disposal. It was determined that the gauge technician knowingly left the gauge in an area of active construction. The technician thought that the mini-dozer operator saw the gauge, took no action to secure the gauge, and observed the dozer run over the gauge. The materials testing company immediately terminated the technician's use of nuclear gauges. They also instituted a company-wide retraining module with a detailed focus on safe practices, appointed an individual to a newly developed role of nuclear gauge safety manager, and implemented a rigid policy on the use and protection of nuclear gauges.

Item Number 210081 - A radioactive source manufacturer received a radioactive material shipment from an oilfield services company on 2/12/2021, with external radiation levels above the regulatory limit. The shipment contained 10 fixed nuclear gauges, each containing a 3.7 or 7.4 GBq (100 or 200 mCi) Cs-137 source. Surveys of the bottom surface of the package revealed greater than 4.4 mSv/hour (440 mrem/hour), with a Transport Index (TI) of 11.1. The lateral sides read 0.75 mSv/hour (75 mrem/hour). The carrier was not an enclosed vehicle. The cause was determined to be equipment degradation of the fixed gauge shielding. Members of the public were possibly overexposed during transportation, but that determination was never finalized. The incident was referred to the Department of Transportation. This event was classified as an EQP and TRS event.

Item Number 210126 - A radiography services company reported that a 4.74 TBq (128 Ci) Ir-192 source failed to fully retract and lock into a radiography exposure device during operations on 2/12/2021. The radiographers secured the area by adjusting their 2 mR/hour boundaries to an unshielded source distance and contacted the company's designated source retrieval person. Upon arrival, the designee surveyed the area and device and found elevated radiation readings. Working the crank assembly handle back and forth several times, he was able to return the source to the secured and locked position. The exposure device was taken out of service and transported back to company's facility for inspection. The cause of the event was believed to be cold temperature and freezing of the lock mechanism. The RSO investigated the incident and found that neither the radiographer nor the assistant radiographer had been performing proper radiation surveys during the workday, which would have identified the lock failure sooner. As a result, the radiographer received a whole-body radiation exposure of 8.76 mSv (876 mrem) and the assistant radiographer received 1.27 mSv (127 mrem). Corrective actions included retraining all radiographers to follow proper procedure. The radiographer's and assistant radiographer's employment was terminated. The Pennsylvania Department of Environmental Protection performed a reactive inspection.

Item Number 210135 - A construction materials testing company reported that a moisture/density gauge was run over by a piece of equipment at a construction site on 4/1/2021. The gauge contained a 1.48 GBq (40 mCi) Am-Be source and a 0.3 GBq (8 mCi) Cs-137 source. The gauge technician was moving his equipment to a new test location when the gauge was damaged. The RSO stated the gauge case was shattered and was not certain how they would recover the gauge. The gauge was reading 0.4 mSv/hour (40 mrem/hour) on contact near the Cs-137 source. A barrier was established around the gauge and the exposure rate readings at the barrier were at background levels. The Texas Department of State Health Services advised the RSO to contact the manufacturer and request assistance in recovering the gauge. The manufacturer could not assist in recovery. The RSO identified that the Cs-137 source was not in the fully shielded position. The source rod was no longer attached to the gauge housing. Because the source rod was bent, the source could not be retracted into the shield. The licensee picked up the source rod with pliers, placed it in a 30-gallon can half-full of sand, then covered the source with sand. The highest exposure rate on the can was 8 µSv/hour (800 µrem/hour). The Am-Be source was not affected by the event. The gauge and sources were transported to the company's storage facility. No individual received a significant radiation exposure from the incident. The manufacturer picked up the gauge and sources for disposal on 4/15/2021. A leak test determined that the Cs-137 source was not leaking.

Item Number 210188 - A panoramic irradiator facility reported receiving several alarms for the Cell B irradiator on 5/1/2021 at approximately 1:40 am. An attempt to lower the source racks was unsuccessful. The source racks were successfully lowered at approximately 4:00 am using an emergency operating procedure for manually lowering the source racks. During that time, the irradiator entrance door remained secured by the safety system interlock. Troubleshooting identified an electrical fault in a junction box that was caused by a degraded wire that short circuited to ground. The degraded wire was replaced on 5/1/2021. After a functional safety system check was performed to determine that all safety systems were operating correctly, the irradiator resumed operations. The irradiator cell was scheduled for a complete re-wire project, utilizing stainless steel rigid conduit throughout the cell for enhanced wire protection. The date of completion was estimated for 12/31/2021.

Item Number 210307 - An oilfield services company reported that a fire at a wellsite in Eddy County, New Mexico, on 5/9/2021 damaged two densitometers, each of which contained a 7.4 GBq (200 mCi) Cs-137 source. Eddy County, Otis, Loving, and Malaga fire departments responded to the incident. The wellsite was secured overnight to allow the damaged equipment to cool. The RSO arrived at the wellsite on the morning of 5/10/2021. Visual inspection revealed that each densitometer received heavy heat damage. Radiation surveys identified that the lead shielding had been compromised. Leak test samples were collected and sent for emergency assay. A perimeter was set up around each densitometer and all personnel were instructed to remain out of the area. Assay results revealed that the source capsules had

not been compromised. The RSO completed removal of supports and clamps that secured the densitometers to the equipment. Using a large crane, the RSO removed the densitometers and placed them in a designated area away from personnel. Bags of barite were placed over the densitometers to reduce exposure rates throughout the operation. The area was roped off and marked to keep individuals from entering. No radiation readings were identified above background. The source head for each densitometer was removed from the process pipe by cutting the four bolts securing the head, saddle, and detector. The source heads were placed into 5-gallon containers with lead bricks and shot. Each 5-gallon container was then placed into a 55-gallon drum. Once centered inside the drum, additional lead bricks and shot were used to further reduce external radiation levels. Radiation levels at one meter confirmed that the package met DOT requirements as a Yellow III package. The 55-gallon drum was transported to the oilfield services company's facility to be prepared for final disposition.

Item Number 210420 - A construction materials testing company reported that a moisture/density gauge was damaged at a construction site on 9/24/2021. The gauge contained a 1.63 GBq (44 mCi) Am-Be source and a 0.407 GBq (11 mCi) Cs-137 source. The gauge was hit by a piece of construction equipment and the source rod was broken off. An inspector from the South Carolina Department of Health and Environmental Control was dispatched to the location and assisted in packing the gauge and source rod into the transport container using remote handling tools and survey instruments. Additional shielding (fill dirt) was added to the transport container. Dose rate readings indicated readings as high as 38 mR/hr on the surface of the transport container and 0.8 mR/hr at one meter. Leak test results showed that the sources were not leaking. The gauge and source rod were transported and secured at the company's temporary storage location and subsequently transferred to the manufacturer for disposal. The root cause of the event was failure to follow procedures. Corrective actions included providing additional training to personnel.

2.7.3 Events Recently Added to NMED That Occurred Prior to FY21

Ten EQP events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
Item Number 190538 - A patient received less dose than prescribed during a gamma knife treatment due to an equipment failure. On 11/4/2019, a mask treatment was being performed using a gamma knife unit that contained Co-60 sources with a total activity of 136.98 TBq (3,702.7 Ci). The treatment was interrupted when the High-Definition Motor Management tracking system lost communication with 1 minute 29 seconds remaining from shot B6 (planned for 2 minutes 13 seconds) and 2 minutes 36 seconds remaining for shot B3 (no treatment was delivered from this shot). The sources safely retracted into their home position and the software prompted the user to reinitiate the system. However, an error message occurred on each attempt to reinitiate the system. The system was then rebooted, but the same error occurred. The patient was removed from the treatment vault and a service call was made to the manufacturer. It was estimated that the patient received between 93% and 96% of the intended 1,800 cGy (rad) to the left frontal target (50% isodose line) during shot B6. However, the patient received none of the prescribed dose of 1,800 cGy (rad) to the right posterior target (90% isodose line) during shot B3. The doctor and patient were informed immediately. The manufacturer's service engineer arrived that same day to troubleshoot the system. New parts were ordered and arrived on 11/5/2019. Following repair and testing of the gamma knife unit, the patient's treatment was completed on 11/5/2019. This event was classified as an EQP and MED event.

Item Number 200257 - A cancer center reported a medical event that involved a high dose rate unit cervix treatment using a tandem and ring with a 192.07 GBq (5.191 Ci) Ir-192 source. After the treatment was completed and the device removed from the patient, it was discovered that the tandem had broken into two pieces. It was unknown where the source was positioned during the treatment. No warnings or errors from the machine were recorded from either the check source or the treatment cable. The source was in the patient for a total of 564.7 seconds. Of that time, the source was in the tandem for a total of 355.2 seconds. The physician and patient were notified of the event. It was determined that the break in the tandem occurred about four inches from the end of the tandem, at the beginning of the bend on the insertion end at the start of the ring. Using the location of the guide wire, it appeared that the source tracked next to the tandem and that the exposure occurred only to the intended tissue. The patient was to receive a total of 2,750 cGy (rad) in five fractions of 550 cGy (rad) each. The patient was receiving the third fraction when the event occurred. The cancer center stated that there was no way to know with certainty where the source was during the time of treatment but believed that the most probable path would have been the same as the markers, which was determined to have traveled along the tandem within 2 mm lateral of the intended position, resulting in minimal dose difference to the intended tissue. If the source did not travel along the tandem after the break, the dose to other possible tissue would have ranged from 450 to 600 cGy (rad). The cancer center stated that had the wire stuck at the cervix, it would have likely caused a fault on the machine because the drive wire for the source is stiffer than the wire for the markers. The final 2 cm of insertion of the marker wire had a small resistance but did not prevent the wire from being fully inserted on a second attempt. The markers were removed prior to treatment and no fluid or abnormalities were observed on the wire. The transverse plane on the CT was not checked inferior of the ring until the device was removed from the patient, which revealed that the markers were outside of the applicator. A contamination survey of the source wire was completed and no contamination was detected. After a comprehensive internal review by the Radiation Oncology Quality Committee with physician and physics leadership, it was determined that the remaining two fractions would be completed. The tandem was first used in March 2019 and was used a total of 53 times prior to this event. The cancer center purchased new, thicker tandems to use in the future. They also modified their procedure to require all views of the markers to be reviewed prior to treatment. They will periodically x-ray the tandems to make sure there are no flaws. The manufacturer investigated the incident but did not identify a root cause. There were no indications that this incident was a trend. All devices can continue to be used as intended. The manufacturer believed that the surface breakage was influenced by the bending process of the tandem during manufacturing and the subsequent forces applied during repeat insertions and sterilizations. Based upon their records, they had seen similar breaks in 0.4% of all bend-manufactured parts (the white plastic material portion of the applicator where the break occurred). Based upon data, no modifications were planned for the tandem. However, the manufacturer evaluated a new method of manufacturing (bending of material), which was expected to reduce the risk of tandem break failure. This event was classified as an EQP and MED event.

2.8 Transportation

2.8.1 Ten-Year Data

Figure 8 displays the annual number and trend of TRS events that occurred during the 10-year period. The trend analysis determined that the Total and NRC-regulated events represent statistically significant decreasing trends (indicated by the trend lines). However, the Agreement State-regulated events do not represent a statistically significant trend (indicated by the absence of a trend line).

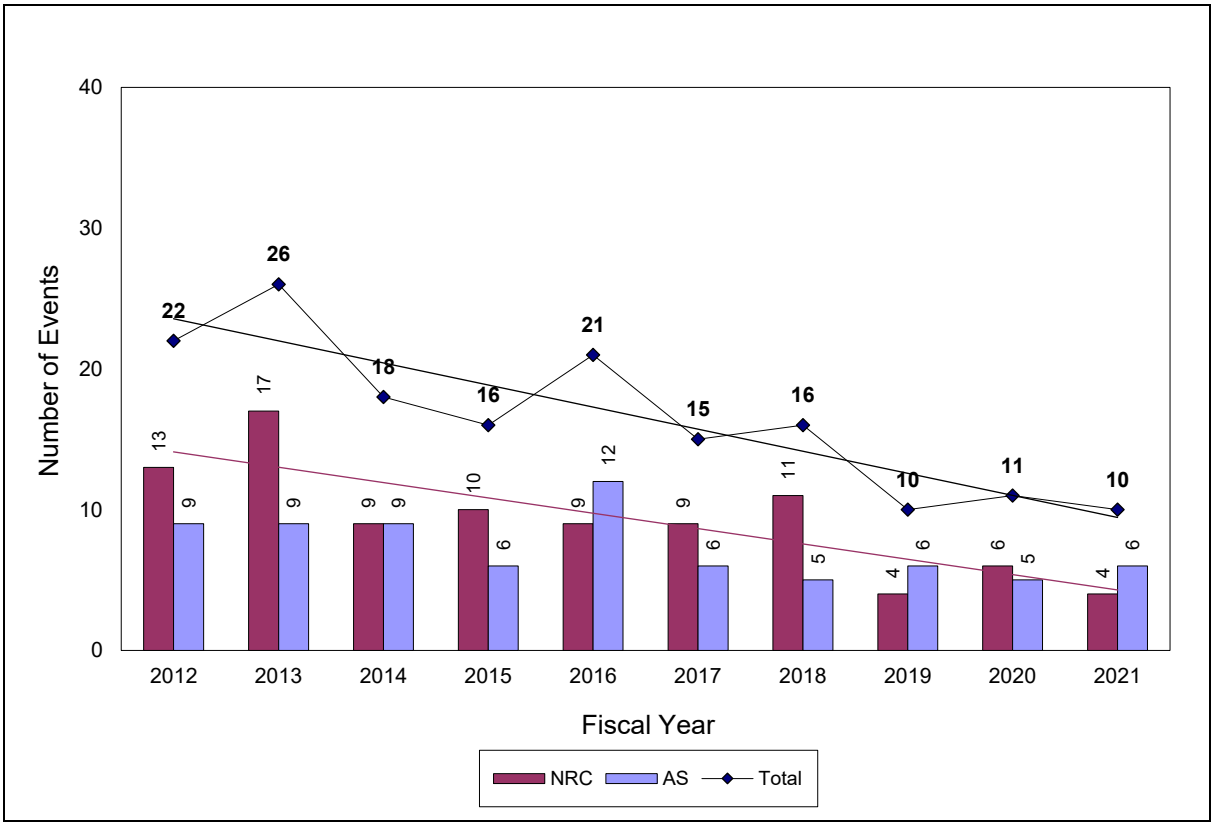

Figure 8. Transportation Events (165 total)

It is not possible to discern the significance of TRS events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.8.2 FY21 Data

Ten TRS events occurred in FY21, none of which were considered significant.

Significant Events
None

Events of Interest
Item Number 200405 - A radioactive source manufacturer received a radioactive material shipment from an oilfield services company on 10/2/2020, with external radiation levels above the regulatory limit. The shipment consisted of five packages, each containing a 555 GBq (15 Ci) of Am-Be source, with each package exceeding the limit. The dose rates ranged from 2.2 to 2.95 mSv/hour (220 to 295 mrem/hour) on contact, with a Transport Index (TI) range of 13 to 15. The common carrier was notified on 10/2/2020.

The oilfield services company stated that the highest dose rate prior to shipment was approximately 0.9 mSv/hour (90 mrem/hour) on contact, with a TI of about 7. They were certain that all of the poly seal plugs were properly screwed into place. They also stated that the shipping containers were very robust and did not believe that the containers could have been damaged during shipping. The radioactive source manufacturer observed that the contents appeared to have shifted to a lower point in the drums (not centered as expected), which would lead to an increase in the external dose rates.

Item Number 210081 - A radioactive source manufacturer received a radioactive material shipment from an oilfield services company on 2/12/2021, with external radiation levels above the regulatory limit. The shipment contained 10 fixed nuclear gauges, each containing a 3.7 or 7.4 GBq (100 or 200 mCi) Cs-137 source. Surveys of the bottom surface of the package revealed greater than 4.4 mSv/hour (440 mrem/hour), with a TI of 11.1. The lateral sides read 0.75 mSv/hour (75 mrem/hour). The carrier was not an enclosed vehicle. The cause was determined to be equipment degradation of the fixed gauge shielding. Members of the public were possibly overexposed during transportation, but that determination was never finalized. The incident was referred to the Department of Transportation. This event was classified as an EQP and TRS event.

2.8.3 Events Recently Added to NMED That Occurred Prior to FY21

Three TRS events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. None of these events were considered significant. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events
None

Events of Interest
None

2.9 Other

2.9.1 Ten-Year Data

Figure 10 displays the annual number of OTH events that occurred during the 10-year period. Because OTH events do not fit a defined criterion that ensures consistency within the data, trending analysis is not performed on this data.

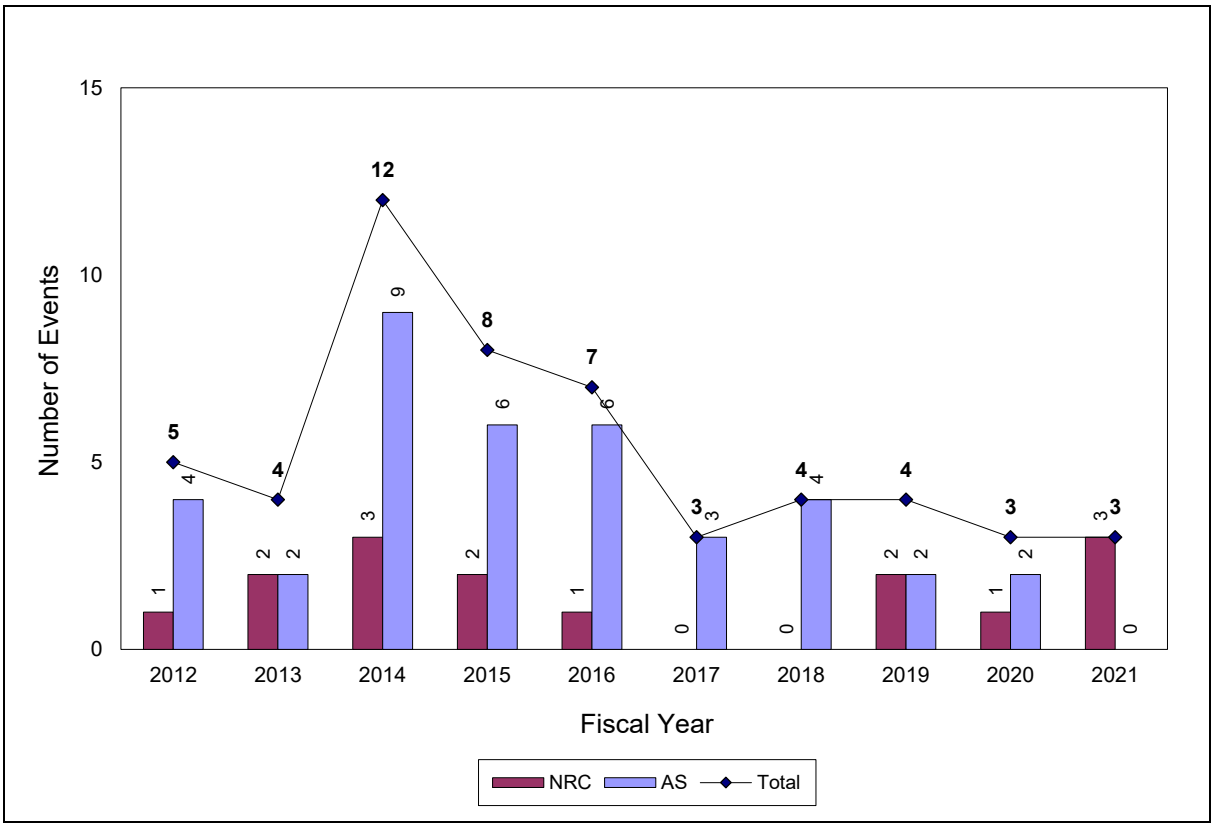

Figure 9. Other Events (53 total)

It is not possible to discern the significance of OTH events strictly from the CFR reporting requirements (as in Sections 2.4 and 2.5). Therefore, event significance will be determined on an event-by-event basis based on the severity of the event (e.g., significant exposure to workers, members of the public, and/or the environment). Events possessing one or more unusual aspects, but that do not meet the significant event threshold, are considered events of interest.

2.9.2 FY21 Data

Three OTH events occurred in FY21, one of which was considered significant.

Significant Events

Item Number 210467 - An embryo/fetus received a radiation dose when a patient who was unknowingly pregnant (or became pregnant shortly afterwards) was administered a therapy treatment of 5.48 GBq (148 mCi) of I-131 on 9/30/2021. The patient received a negative pregnancy test prior to the treatment. At a later date, the patient realized that she was pregnant and estimated the date of conception to be either 9/29/2021 or 10/10/2021. The RSO estimated the dose to the embryo/fetus to be 394 mSv (39.4 rem) based on a conception date of 9/29/2021. The estimated dose to the embryo/fetus would be 1.7 mSv (0.17 rem) based on a conception date of 10/10/2021. This event was classified as a potential Abnormal Occurrence.

Events of Interest

Item Number 210123 - Dose rates exceeded the 2 mR/hr limit for unrestricted areas at a research reactor. During maintenance activities on the Mo-99/Tc-99m generator production line on 3/4/2021, multiple vials containing a total of 481 GBq (13 Ci) of Mo-99 were temporarily moved from inside the hot cell to an attached shielded glove box to reduce dose rates in the work area. The contents of these vials were from flushing the system to ensure that the system was primed for the next production run. On the morning of 3/5/2021, a radiation worker moved the vials to an adjacent piece of equipment for temporary storage, thinking that the vials were decayed samples ready for removal per routine practice. During a routine laboratory survey at approximately 3:00 pm on 3/5/2021, a health physics technician (HPT) discovered that the material had created an elevated dose rate within the laboratory space. The HPT exited the laboratory and secured the room. On 3/8/2021, the vials were returned to the hot cell for long-term storage. At the time of the incident, dose rates within the posted radiation work area were approximately 10 mSv/hr (1,000 mrem/hr) on contact, and 5 mSv /hr (500 mrem/hr) at 30 cm. An evaluation showed that the dose rate external to the building (an unrestricted area) was 0.1 mSv/hr (10 mrem/hr) on contact with the building, and 0.07 mSv/hr (7 mrem/hr) at 30 cm. The dose rate on a nearby walking path was less than 0.005 mSv/hr (0.5 mrem/hr); camera footage showed that no person walked closer to the building than the walking path. A review of camera footage, badge reader logs, and electronic dosimetry found that no member of the public received any measurable dose from this event. All radiation workers were monitored with electronic dosimetry and did not exceed any level of exposure beyond normal work conditions. This event was caused by a lack of communication and the lack of HPT involvement when the radiation worker moved the vials. Subsequent surveys on 7/14/2021 and 7/21/2021 identified additional areas on the building's external walls with dose rates exceeding 2 mR/hr. One area measuring 0.2 mSv/hr (20 mrem/hr) on contact was 10-12 feet above ground level and was caused by 11.1 GBq (300 mCi) of I-131 in a glovebox; additional shielding was added to the glovebox to reduce dose rates below limits. Another area measuring 0.3 mSv/hr (30 mrem/hr) on contact was approximately 15 feet above ground level and occurred during the short period (1-2 minutes) when 3.7 TBq (100 Ci) of Lu-177 was being moved from pigs into an autoclave. It is unknown whether any member of the public received dose. These issues were caused by a lack of understanding of shielding requirements, shielding not being used in its designed configuration, and inadequate surveys. Corrective actions included personnel training and procedure changes.

2.9.3 Events Recently Added to NMED That Occurred Prior to FY20

No OTH events were recently added to NMED that occurred prior to the current fiscal year and had not been included in any previous annual report. Note that this data may differ from the associated Appendix D graph, which displays the number of events added and subtracted from specific years within the most recent 10-year period, including events moved between years due to changes in the recorded event date.

Significant Events

None

Events of Interest

None

Appendix A

Event Type Descriptions and Criteria

Appendix A
Event Type Descriptions and Criteria

NMED events covered by this report are divided into the following categories based on the event reporting requirements defined in 10 CFR. Note that the tables in this appendix do not contain the full text of the applicable CFRs.

Lost/Abandoned/Stolen Material (LAS)

The LAS event category includes those events where licensed radioactive material is lost or found, abandoned or discovered, and stolen or recovered. The radioactive material involved can be sealed or unsealed material, specifically or generally licensed, exempt or non-exempt quantities, involve a licensee or a non-licensee, and can be found anywhere. Abandoned well logging sources are included in this category.

NMED LAS reportable events are those that meet the reporting requirements of 10 CFR Part 20.2201. Events that do not meet the 20.2201 reporting requirement thresholds are captured as not-reportable LAS events. Additionally, LAS events involving non-Atomic Energy Act material are entered into NMED as not-reportable events.

All reportable LAS events will be coded as one of the following reporting requirements. For events involving more than one source, the decision of 10 × or 1,000 × the 10 CFR Part 20 Appendix C quantity is based on the aggregate quantity of licensed material.

Table A-1. Primary LAS Reporting Requirements

Primary LAS Reporting Requirements	Reporting Requirement Summary
20.2201(a)(1)(i)	Aggregate activity ≥ 1,000 × 10 CFR Part 20 Appendix C quantity
20.2201(a)(1)(ii)	Aggregate activity > 10 and < 1,000 × 10 CFR Part 20 Appendix C quantity
39.77(d)	Irretrievable well logging source

The following additional (secondary) CFRs will be added as applicable. This should occur infrequently. For the 10 CFR 37 requirements, the event will instead be coded as OTH if there was no actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material.

Table A-2. Secondary LAS Reporting Requirements

Secondary LAS Reporting Requirements	Reporting Requirement Summary
30.55(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H 3 (not generally licensed).
37.57(a)	Unauthorized entry resulted in actual ~~or attempted~~ theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(a)	A shipment of category 1 quantities of material is lost or missing.
37.81(b)	A shipment of category 2 quantities of material is lost or missing.
37.81(c)	Actual ~~or attempted~~ theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	Actual ~~or attempted~~ theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
37.81(e)	Recovery of any lost or missing shipment of category 1 quantities of material.
37.81(f)	Recovery of any lost or missing shipment of category 2 quantities of material.

39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
40.64(c)(1)	Theft/diversion of 15 lb (or 150 lb per year) of source material (uranium or thorium).
73.71(a)(1)	Lost shipment of any SNM.
73.App G(I)(a)(1)	Actual or attempted theft or unlawful diversion of SNM.
74.11(a)	Loss, theft or unlawful diversion (actual or attempted) of SNM or the unauthorized production of enriched uranium.
76.120(a)(2)	Loss, other than normal operating loss, of special nuclear material.
76.120(a)(3)	Actual or attempted theft or unlawful diversion of special nuclear material.
150.16(b)(1)	Actual or attempted theft or unlawful diversion of SNM.
150.17(c)(1)	Attempted theft or unlawful diversion of more than 6.8 kg (15 lb) of Uranium or Thorium at any one time or more than 68 kg (150 lb) in any one calendar year.
150.19(c)	Theft/diversion of 10 Ci (or 100 Ci per year) of H-3 (not generally licensed). Note: This requirement is just like 30.55(c), but applies to Agreement States and offshore waters.

Medical (MED)

MED events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-3. MED Reporting Requirements

MED Reporting Requirements	Reporting Requirement Summary
35.3045(a)(1)(i)(A)	Total dose delivered that differs from the prescribed dose by 20% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(i)(B)	Total dosage delivered that differs from the prescribed dosage by 20% or more or falls outside the prescribed range; and results in a dose that differs from prescribed by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(i)(C)	Fractionated dose delivered that differs from the prescribed dose for a single fraction by 50% or more; and differs from the prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(A)	Administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(B)	Administration of a radioactive drug containing byproduct material by the wrong route of administration that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(C)	Administration of a dose or dosage to the wrong individual or human research subject that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(D)	Administration of a dose or dosage delivered by the wrong mode of treatment that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(ii)(E)	Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.
35.3045(a)(1)(iii)	Dose to the skin, organ, or tissue, other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.
35.3045(a)(2)(i)	For permanent implant brachytherapy, the total source strength administered differs by 20% or more from the total source strength documented in the post-implant portion of the written directive, excluding sources that were implanted in the correct site but migrated outside of the treatment site.
35.3045(a)(2)(ii)	For permanent implant brachytherapy, the total source strength administered outside of the treatment site exceeds 20% of the total source strength documented in the post-implant portion of the written directive, excluding sources that were implanted in the correct site but migrated outside of the treatment site.
35.3045(a)(2)(iii)(A)	For permanent implant brachytherapy, an administration that includes the wrong radionuclide.
35.3045(a)(2)(iii)(B)	– For permanent implant brachytherapy, an administration that includes the wrong individual or research subject.
35.3045(a)(2)(iii)(C)	For permanent implant brachytherapy, an administration that includes sealed sources implanted directly into a location discontiguous from the treatment site, as documented in the post-implant portion of the written directive.
35.3045(a)(2)(iii)(D)	For permanent implant brachytherapy, an administration that includes a leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

35.3045(b)	Event resulting from patient intervention in which the administration of byproduct material or radiation from byproduct material results in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Events are not considered MED events if they involve:

- Only a linear accelerator,
- Doses administered in accordance with a written directive (even if the directive is in error), or
- Patient intervention, unless the event results in unintended permanent functional damage to an organ or physiological system.

Events are considered MED events if, for example, a linear accelerator is used for therapy by mistake instead of a teletherapy unit or a teletherapy unit instead of a linear accelerator.

For purposes of determining whether to categorize an event as MED or EXP, MED events occur to patients only (i.e., those being administered a medical procedure). For example, if a patient receives too much dose during a procedure, the event would be categorized as MED rather than EXP. However, radiation exposure received from a cause other than the patient's medical procedure may be categorized as EXP.

Radiation Overexposure (EXP)

EXP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-4. EXP Reporting Requirements

EXP Reporting Requirements	Reporting Requirement Summary
20.2202(a)(1)(i)	An individual received a total effective dose equivalent of 25 rem (0.25 Sv) or more.
20.2202(a)(1)(ii)	An individual received a lens dose equivalent of 75 rem (0.75 Sv) or more.
20.2202(a)(1)(iii)	An individual received a shallow-dose equivalent to the skin or extremities of 250 rad (2.5 Gy) or more.
20.2202(b)(1)(i)	Loss of control of material causing or threatening to cause an individual to receive a total effective dose equivalent exceeding 5 rem (0.05 Sv) in a period of 24 hours.
20.2202(b)(1)(ii)	Loss of control of material causing or threatening to cause an individual to receive an eye dose equivalent exceeding 15 rem (0.15 Sv) in a period of 24 hours.
20.2202(b)(1)(iii)	Loss of control of material causing or threatening to cause an individual to receive a shallow-dose equivalent to the skin or extremities exceeding 50 rem (0.5 Sv) in a period of 24 hours.
20.2203(a)(2)(i)	Doses in excess of the occupational dose limits for adults in 20.1201.
20.2203(a)(2)(ii)	Doses in excess of the occupational dose limits for a minor in 20.1207.
20.2203(a)(2)(iii)	Doses in excess of the limits for an embryo/fetus of a declared pregnant woman in 20.1208.
20.2203(a)(2)(iv)	Doses in excess of the limits for an individual member of the public in 20.1301.
20.2203(a)(2)(v)	Doses in excess of any applicable limit in the license.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

The EXP event category includes all regulatory overexposures of radiation workers or exposures of members of the public to radiation. The overexposure can be external or internal and can be whole body, extremity, skin, lens of the eye, or internal dose. When the overexposure involves multiple individuals or an individual with multiple overexposure types (such as whole body and extremity), the different types of overexposures are entered separately. Note that dosimeters record exposure if improperly stored near a radiation source and, depending on the type of dosimeter, may react as though they are in a radiation field when exposed to heat or humidity.

It is NRC policy to classify only those events that positively involve a personnel overexposure, and not just a dosimeter exposure, as reportable EXP events. For example, either the licensee does not contest the personnel overexposure, or in cases where the licensee does contest the overexposure, the State or NRC determines the event to be personnel overexposure.

EXP limits do not apply to patients receiving medical procedures.

Release of Licensed Material or Contamination (RLM)

RLM events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-5. RLM Reporting Requirements

RLM Reporting Requirements	Reporting Requirement Summary
20.2202(a)(2)	Release of radioactive material, inside or outside of a restricted area, so that had an individual been present for 24 hours, the individual could have received an intake 5 times the ALI.
20.2202(b)(2)	Release of material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of 1 ALI.
20.2203(a)(2)(vi)	Doses in excess of the ALARA constraints for air emissions established under 20.1101(d).
20.2203(a)(3)(i)	Radiation or concentrations of radioactive material in a restricted area in excess of any applicable limit in the license.
20.2203(a)(3)(ii)	Radiation or concentrations of radioactive material in an unrestricted area in excess of 10 times any applicable limit set forth in Part 20 or in the license.
20.2203(a)(4)	Levels of radiation or releases of radioactive material in excess of the standards in 40 CFR Part 190, or of license conditions related to those standards.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(1) 40.60(b)(1) 70.50(b)(1) 76.120(c)(1)	Unplanned contamination event that requires access to be restricted for > 24 hours, involves > 5 times the lowest ALI, and has access restricted for a reason other than to allow isotopes with a half-life of < 24 hours to decay.
30.50(b)(3) 40.60(b)(3) 70.50(b)(3) 76.120(c)(3)	Event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.
50.72(b)(3)(xii) 72.75(c)(3)	Event requiring the transport of a radioactively contaminated person to an offsite medical facility for treatment.

The RLM event category includes two types of events. The first type is a radioactive release to air or water exceeding the 10 CFR Part 20 Appendix B annual limit on intake (ALI). The second type of RLM event involves contamination events such as a radioactive spill outside of work areas, removable contamination found on equipment, or material tracked around a laboratory such that additional radiological control measures had to be implemented. This category does not include spills inside of laboratory hoods, radiopharmaceutical dose preparation areas, or hot cells where radioactive work routinely requires cleanup or changing of absorbent paper after the performance of a task. Should there be multiple release types (e.g., surface, air, water, or person) or areas of contamination associated with the release, this information is entered individually.

Leaking Sealed Source (LKS)

LKS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-6. LKS Reporting Requirements

LKS Reporting Requirements	Type of Source
31.5(c)(5)	Generally licensed
34.27(d)	Radiography
35.67(e)	Medical
39.35(d)(1)	Well logging (leaking)
39.77(a)	Well logging (ruptured)
30.50(b)(2)	All other sources

The NRC requires that most sealed sources be periodically leak tested to verify that the material is still sealed and that the source is still considered safe to use without contamination controls, including protective clothing or gloves. Sources are generally exempt from leak testing under the following conditions [see 10 CFR Part 31.5(c)(2), 34.27(c), 35.67(f), and 39.35(e)]:

- Sources containing only gaseous radioactive material (like H-3, Kr-85, etc.),
- Sources containing licensed material with a half-life of 30 days or less,
- Sources containing <= 100 μCi of other beta and/or gamma emitting material,
- Sources containing <= 10 μCi of alpha emitting material,
- Sources held in storage in the original shipping container prior to initial installation,
- Seeds of Ir-192 encased in nylon ribbon, or
- Sources in storage and not in use (must be leak tested prior to use or transfer).

A source is considered leaking if a leak test can detect greater than 0.005 μCi of removable radioactive material. The leaking source is then removed from service, disposed of or returned to the manufacturer for repair, and a report is sent to the NRC or Agreement State with the details of the leaking source.

For regulatory reporting purposes, a leaking source is generally considered a failed device under 10 CFR Part 30. Therefore, in most cases an LKS event is also coded as an EQP event. An exception is the Ni-63 foil source, which is coded as only an LKS event.

Equipment (EQP)

EQP events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-7. EQP Reporting Requirements

EQP Reporting Requirements	Reporting Requirement Summary
21.21(d)(1)(i)	A failure to comply or a defect affecting the construction or operation of a facility or an activity that is subject to licensing requirements.
21.21(d)(1)(ii)	A failure to comply or a defect affecting a basic component that is supplied for a facility or an activity that is subject to licensing requirements.
30.50(a) 40.60(a) 70.50(a) 76.120(b)	Event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of material that could exceed regulatory limits.
30.50(b)(2) 40.60(b)(2) 70.50(b)(2) 72.75(d)(1) 76.120(c)(2)	Equipment is disabled or fails to function as designed.
30.50(b)(4) 40.60(b)(4) 70.50(b)(4) 76.120(c)(4)	Unplanned fire or explosion that damages any licensed material or any device, container, or equipment containing licensed material.
31.5(c)(5)	Actual or indicated failure to shielding, the on-off mechanism or indicator, or upon the detection 0.005 uCi or more of removable radioactive material.
34.101(a)(1)	Unintentional disconnection of the radiographic source assembly from the control cable.
34.101(a)(2)	Inability to retract and secure the radiographic source assembly to its fully shielded position.
34.101(a)(3)	Failure of any radiographic component (critical to the safe operation of the device) to properly perform its intended function.
35.3204	Eluate exceeding the permissible concentration of Mo-99, Sr-82, and Sr-85, as listed in 35.204(a), at the time of generator elution; more than 0.15 kBq Mo-99 per MBq Tc-99m, more than 0.02 kBq Sr-82 per MBq Rb-82 chloride, or more than 0.2 kBq Sr-85 per MBq Rb-82 chloride.
36.83(a)(1)	An irradiator source stuck in an unshielded position.
36.83(a)(2)	Fire or explosion in an irradiator radiation room.
36.83(a)(3)	Damage to the irradiator source racks.
36.83(a)(4)	Failure of the irradiator cable or drive mechanism used to move the source racks.
36.83(a)(5)	Inoperability of the irradiator access control system.
36.83(a)(6)	Detection of irradiator source by the product exit monitor.
36.83(a)(7)	Detection of irradiator radioactive contamination attributable to licensed radioactive material.
36.83(a)(8)	Structural damage to the irradiator pool liner or walls.
36.83(a)(9)	Abnormal water loss or leakage from the irradiator source storage pool.
36.83(a)(10)	Irradiator pool water conductivity exceeding 100 microsiemens per centimeter.
39.77(a)	Ruptured well logging sealed source.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

72.75(c)(1)	Defect in any spent fuel, HLW, or reactor-related GTCC waste storage structure, system, or component that is important to safety.
72.75(c)(2)	Significant reduction in the effectiveness of any spent fuel, HLW, or reactor-related GTCC waste storage confinement system during use.
72.242(d)	Design or fabrication deficiency for any spent fuel storage cask delivered to a licensee which affects the ability of components important to safety to perform their safety function.

The EQP event category includes all types of radiological equipment problems, including generally licensed device problems covered in 10 CFR Part 31; radiography equipment problems covered in 10 CFR Part 34; irradiator problems covered in 10 CFR Part 36; well logging problems covered in 10 CFR Part 39, and other types of equipment covered in 10 CFR Part 30, 40, 70, and 76. EQP events are defined as the failure of, or a defect in, any piece of equipment that either contains licensed radioactive materials as an integral part, or whose function is to interact with such materials.

Transportation (TRS)

TRS events are determined and coded per the 10 CFR reporting requirements listed below.

Table A-8. TRS Reporting Requirements

TRS Reporting Requirements	Reporting Requirement Summary
20.1906(d)(1)	Transported package exceeds removable surface contamination limits.
20.1906(d)(2)	Transported package exceeds external radiation limits.
71.5	Transportation of licensed material.
71.95(a)(1)	Significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use.
71.95(a)(2)	Defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.
71.95(a)(3)	Conditions of approval in the Certificate of Compliance were not observed in making a shipment.
71.95(b)	Conditions in the Certificate of Compliance were not followed during a shipment.

Other (OTH)

The OTH event category includes the following types of events:

1. Doses to an embryo/fetus or nursing child reportable per 10 CFR Part 35.3047. Note that these events are not MED events (reportable per 10 CFR Part 35.3045).
2. Dose in an unrestricted area in excess of 2 mrem in an hour, but no individual received a dose in excess of limits (if a dose in excess of limits is received, the event is an EXP event).
3. 10 CFR 37 events that do not result in the actual theft, sabotage, or diversion of Category 1 or 2 quantities of radioactive material. Otherwise, the event is as an LAS event.
4. Reportable events that do not specifically fit into one of the previous event types.

For items 1-3 above, OTH events are determined and coded per the 10 CFR reporting requirements listed below. Due to the nature of item 4 above, other reporting requirements may also be used.

Table A-9. OTH Reporting Requirements

OTH Reporting Requirements	Reporting Requirement Summary
20.2203(a)(2)(iv)	Dose in an unrestricted area in excess of 2 mrem in an hour, but no dose received in excess of limits.
35.3047(a)	Dose to an embryo/fetus greater than 50 mSv (5 rem) DE from administration of byproduct material or radiation from byproduct material to a pregnant individual unless specifically approved, in advance, by the authorized user.
35.3047(b)(1)	Dose to a nursing child greater than 50 mSv (5 rem) TEDE resulting from an administration of byproduct material to a breast-feeding individual.
35.3047(b)(2)	Dose to a nursing child resulting in unintended permanent functional damage to an organ or physiological system, as determined by a physician, resulting from an administration of byproduct material to a breast-feeding individual.
37.57(a)	Unauthorized entry resulted in ~~actual or~~ attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of material.
37.57(b)	Suspicious activity related to possible theft, sabotage, or diversion of a category 1 or category 2 quantity of material
37.81(c)	~~Actual or~~ attempted theft or diversion (or related suspicious activities) of a shipment of category 1 quantities of material.
37.81(d)	~~Actual or~~ attempted theft or diversion (or related suspicious activities) of a shipment of category 2 quantities of material.
39.77(b)	Theft or loss of radioactive material, radiation overexposures, excessive levels and concentrations of radiation for events involving well logging operations, and certain other accidents.

Appendix B

Statistical Trending Methodology

Appendix B
Statistical Trending Methodology

General

The following is a general discussion of statistical trending techniques.

A common approach to the statistical analysis of trend is based on regression methods. In particular, it is often the case that a relationship exists between the values assumed by a pair of variables. For example, if x is time (in years), and y is the rate of events per year, then we could use regression methods to study whether there is a relationship between time and event rate.

Regardless of the application, it is standard practice to refer to x as the independent variable and y as the dependent variable. Another common term for the dependent variable is "response variable," and the terms covariant and explanatory variable are sometimes used for the independent variable. Also, it is typical with regression modeling that the independent variable can be measured with little or no error, but the dependent variable involves a random error. Consequently, even if there is a deterministic functional relationship between the two variables, when data pairs (x_1, y_1), (x_2, y_2),..., (x_n, y_n) are plotted, the points will not coincide exactly with the function, but instead will tend to be scattered. Such a plot is called a scatter diagram and shows the variation in the data. The plots in this report are bar charts containing the same information.

Fitting a Straight Line to Data

Consider a linear function

$$f(x) = \alpha + \beta x \tag{B-1}$$

where α and β are unknown parameters. A common model is that y is the sum of a linear function of the form (1) and a random error term, e. Standard results on estimation and inference about the parameters of the model assume that e is a normally distributed random variable with mean 0 and constant (but unknown) variance, σ^2. These assumptions mean that:

- Each yi is an observed value of a random quantity that is normally distributed [with mean f(xi)], and
- All the observations yi are of variables with a common variance, σ2.

The y_i are also assumed to be observations of random quantities that are independent of each other.

Under these conditions, the usual approach to estimating the unknown parameters α and β is the method of least squares (LS). In this method, α and β are selected so that the sum of the squares of the vertical distances between the data points and the fitted line is as small as possible. The LS method leads to the estimates

$$\hat{\beta} = \frac{\sum_{i=1}^{n}(x_i - \bar{x})y_i}{\sum_{i=1}^{n}(x_i - \bar{x})^2} \text{ and} \tag{B-2}$$

$$\hat{\alpha} = \bar{y} - \hat{\beta}\bar{x}\,, \tag{B-3}$$

where $\bar{x}$ and $\bar{y}$ are arithmetic averages. The estimated LS regression line is then

$$\hat{y} = \hat{\alpha} - \hat{\beta}x\,, \tag{B-4}$$

and an estimate of σ is

$$s = \sqrt{\frac{\sum_{i=1}^{n} (y_i - \hat{y}_i)^2}{n-2}} \,. \tag{B-5}$$

Testing for Trend

A trend exists whenever the true slope, β, is not zero. We start the analysis with the idea that β is zero, and then ask whether the data tell us otherwise. Two quantities computed from the data are used in this assessment. The first, the *error sum of squares* (SSE), appears in the numerator of s. It is defined as

$$SSE = \sum_{i=1}^{n} (y_i - \hat{y}_i)^2 \,. \tag{B-6}$$

This quantity is the number that is minimized in order to find the estimates of α and β. The differences being squared in SSE represent random variations that remain after the linear fitting process. The second quantity is the *regression sum of squares* (SSR), defined by the following equation

$$SSR = \sum_{i=1}^{n} (\hat{y}_i - \bar{y})^2 \,. \tag{B-7}$$

Note that SSR looks at deviations between the fitted line and the default notion that the data are constant and have no slope.

One can show by algebra that

$$SSE + SSR = SST \,, \tag{B-8}$$

where the *total sum of the squares* (SST), is defined as

$$SST = \sum_{i=1}^{n} (y_i - \bar{y})^2 \,. \tag{B-9}$$

SST measures the overall variation in the data. It is the numerator that would be used to estimate the variance in a sample from a normally-distributed random variable, where all the data in the sample have the same distribution (and thus no trend). This variance measures "random variation" in such a sample.

In the framework of the linear function (1), the regression's effectiveness is measured by the *SSR* term defined above. When it is small, the fitted curve will not differ very much from the horizontal line $y = \bar{y}$. *SSE* will be approximately equal to *SST*, and, from the data, both *SSE* and *SST* will be estimates of mere random variation. In this case, the data does not provide evidence that β is different from zero.

On the other hand, if the y values tend to vary linearly with respect to the independent variable, x, then some of the variation in the y values can be attributed to this dependence on x. Since *SSR* assesses the difference between the least squares predictions of the y values and the arithmetic mean, $\bar{y}$, it is a measure of the variation which is "explained" by the linear relationship. When the slope of the fitted line is large, more of these differences will tend to be large, resulting in a large value of *SSR*.

In the equation, $SST = SSE + SSR$, the total variation is partitioned into two parts, the variation due to random error and the variation due to the linear relationship. The fraction of the total variation that is due to the linear relationship is called the coefficient of determination, or r^2, and is defined by:

$$r^2 = \frac{SSR}{SST} \,. \tag{B-10}$$

r^2 is a fraction that varies from 0 to 1. It will be near 0 if most of the variation is due to randomness, and it will be near 1 if most of the variation is due to the linear relationship.

The closeness to 1 needed for the data to show that the slope is not zero depends on the number of data points. If the dependent data are independent, normally-distributed at each x, with constant variance, and no trend, then the quantity, F, defined by

$$F = \frac{(n-2)\,r^2}{1-r^2} \tag{B-11}$$

can be shown to have an F distribution with degrees of freedom 1 and $n - 2$, where n is the number of data points. When the data satisfy the assumptions except that there is a significant trend, r^2 will be closer to 1 and the computed F statistic will be much larger. Specifically, if the computed F exceeds the upper fifth percentile of the F distribution with 1 and $n - 2$ degrees of freedom, we infer that the data contain evidence that β is not zero, at the 5% level of significance. In this case, we reject the null hypothesis that $\beta = 0$ and conclude that a statistically significant trend exists, with 95% confidence.

As an example, for an assumed set of data fit to the linear model, assume the $r^2 = 0.9369$ and that n is 13. Then the calculated F is 163.3. The upper 95th percentile of the $F(1,11)$ distribution is 4.84. Since 163.3 far exceeds the upper 95th F percentile, the linear model is statistically significant. In this example, the data show that it would be very unlikely for a trend not to exist. The linear model explains too much of the variation in the data for a trend not to exist.

Applying the Model to NMED Data

The method described above was applied for each category of NMED event data, for the overall NMED data, and for additional subgroups of data when trends were found in the overall data. When the calculated F exceeded the 95th percentile, the trend line was shown on the graph and identified as being statistically significant.

In future reports, methods slightly different than that explained above could be employed because NMED data in many cases does not follow the assumptions listed above. In particular, three considerations apply.

- The data are counts, and thus are discrete rather than being normally distributed. This problem is most pronounced when the counts are relatively low or sparse. Also, normally-distributed data in general can be negative, but the counts are always greater than or equal to zero.
- Variations in counts tend to increase as the counts increase. If the events occur at random, with a constant occurrence rate in a particular year or quarter, then the variance of the count for that year or quarter is equal to the mean or average for that year or quarter. Thus, the assumption of a constant variance for the data in each year may not apply.
- Finally, more than one count can be associated with a single reported incident in a single event category. This situation would occur, for example, if several pieces of equipment fail in an event or if several types of overexposure occur. In these cases, the data are not independent.

One way to address the first two concerns is to identify the number of licensees in various NMED categories and study the event occurrence rates rather than the counts. The rates are more likely to come from a continuum and might have a more constant variance.

Taking logarithms of the counts and then applying the LS method avoids the problem of possible negative trend lines. The resulting models can be converted back to the scale of the counts after the regression line is identified. In the scale of the counts, the resulting trend, if any, has a slight curvature.

Weighted regression is a method similar to the LS method described above, but it compensates explicitly for the effect of the different variances from year to year.

Another approach that deals with the first two concerns is to apply regression methods that have been designed specifically for counts. Poisson regression, for example, is based on the idea that the data in each

time period are counts observed from a Poisson distribution, with an occurrence rate that is described by the model. Given occurrence rates in each time period, and independent counts, the probability of seeing the observed data is easily computed by multiplying the occurrence probabilities for the individual time periods. The slope and intercept parameter estimates are selected so that the model maximizes the resulting "likelihood function."

The third issue may have little effect on the results of a trend analysis, as long as there are many counts with relatively few occurring in clumps, no trends in the occurrence of clumps, and no large clumps of counts coming from a single occurrence report. The best way to address the dependence issue is to identify and remove the duplicate counts prior to the trend analysis.

Appendix C

IAEA Radionuclide Categorization

Appendix C
IAEA Radionuclide Categorization

Table C-1 lists the radionuclides that this report uses to determine the significance for events involving the loss, abandonment, or theft of radioactive sources. This list is derived from the IAEA *Code of Conduct on the Safety and Security of Radioactive Sources (2004)* and from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*. Based on the amount of radioactivity involved, the radionuclides are grouped into five categories, with Category 1 being the most hazardous. These categories may be summarized as follows (derived from IAEA Safety Guide RS-G-1.9, *Categorization of Radioactive Sources*):

Category 1: **Extremely dangerous.** These sources could cause permanent injury within a few minutes if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from a few minutes to an hour.

Category 2: **Very dangerous.** These sources could cause permanent injury within minutes to hours if handled. Doses could be fatal to someone in close proximity to an unshielded source for periods ranging from hours to days.

Category 3: **Dangerous.** These sources could cause permanent injury within hours if handled. Doses could possibly (but unlikely) be fatal to someone in close proximity to an unshielded source for periods ranging from days to weeks.

Category 4: **Unlikely to be dangerous.** These sources would not cause permanent injury, although delayed health effects are possible. Doses could possibly (but unlikely) cause temporary injury to someone in close proximity to an unshielded source for a period of many weeks.

Category 5: **Most unlikely to be dangerous.** These sources would not cause permanent injury.

Table C-1. IAEA Code of Conduct Category 1 through 5 Radionuclide Activity Thresholds

Radionuclide	Category 1		Category 2		Category 3		Category 4		Category 5	
	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]	TBq	Ci [1]
Am-241	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Am-241/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Cf-252	20	541	0.2	5.4	0.02	0.54	0.0002	0.0054	1.0e-08	2.7e-07
Cm-244	50	1,352	0.5	13.5	0.05	1.35	0.0005	0.0135	1.0e-08	2.7e-07
Co-60	30	811	0.3	8.1	0.03	0.81	0.0003	0.0081	1.0e-07	2.7e-06
Cs-137	100	2,703	1.0	27.0	0.10	2.70	0.001	0.0270	1.0e-08	2.7e-07
Gd-153	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-05	2.7e-04
Ir-192	80	2,162	0.8	21.6	0.08	2.16	0.0008	0.0216	1.0e-08	2.7e-07
Pm-147	40,000	1,081,200	400.0	10,812.0	40.00	1,081.20	0.4	10.8120	1.0e-05	2.7e-04
Pu-238	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Pu-239/Be	60	1,622	0.6	16.2	0.06	1.62	0.0006	0.0162	1.0e-08	2.7e-07
Ra-226	40	1,081	0.4	10.8	0.04	1.08	0.0004	0.0108	1.0e-08	2.7e-07
Se-75	200	5,406	2.0	54.1	0.20	5.41	0.002	0.0541	1.0e-06	2.7e-05
Sr-90 (Y-90)	1,000	27,030	10.0	270.3	1.00	27.03	0.01	0.2703	1.0e-08	2.7e-07
Tm-170	20,000	540,600	200.0	5,406.0	20.00	540.60	0.2	5.4060	1.0e-06	2.7e-05
Yb-169	300	8,109	3.0	81.1	0.30	8.11	0.003	0.0811	1.0e-05	2.7e-04

Notes

1. The primary values are given in TeraBequerel (TBq). Curie (Ci) values are provided for practical usefulness only and are rounded after conversion.

Appendix D

Revision of Data

Appendix D
Revision of Data

NMED is a dynamic database with new reports and revisions to previous reports being added on a continuing basis. This activity can result in additions or subtractions to data that was published in previous issues of this report. Numerical changes in NMED numbers can result from several different types of technical changes to coded data. The most common types of changes to database records are:

- Record additions due to late reporting
- Record additions or subtractions due to changes in event type
- Changes between fiscal years due to event date changes on individual events
- Record additions or subtractions due to changes in event reportability
- Record additions or subtractions due to reclassifying a single combined event as multiple individual events (or vice versa)
- Record deletions due to duplicated records or NRC direction

Figures D-1 through D-9 below display the changes in the data published in the previous annual report. A positive value indicates that records were added and a negative value indicates that records were removed.

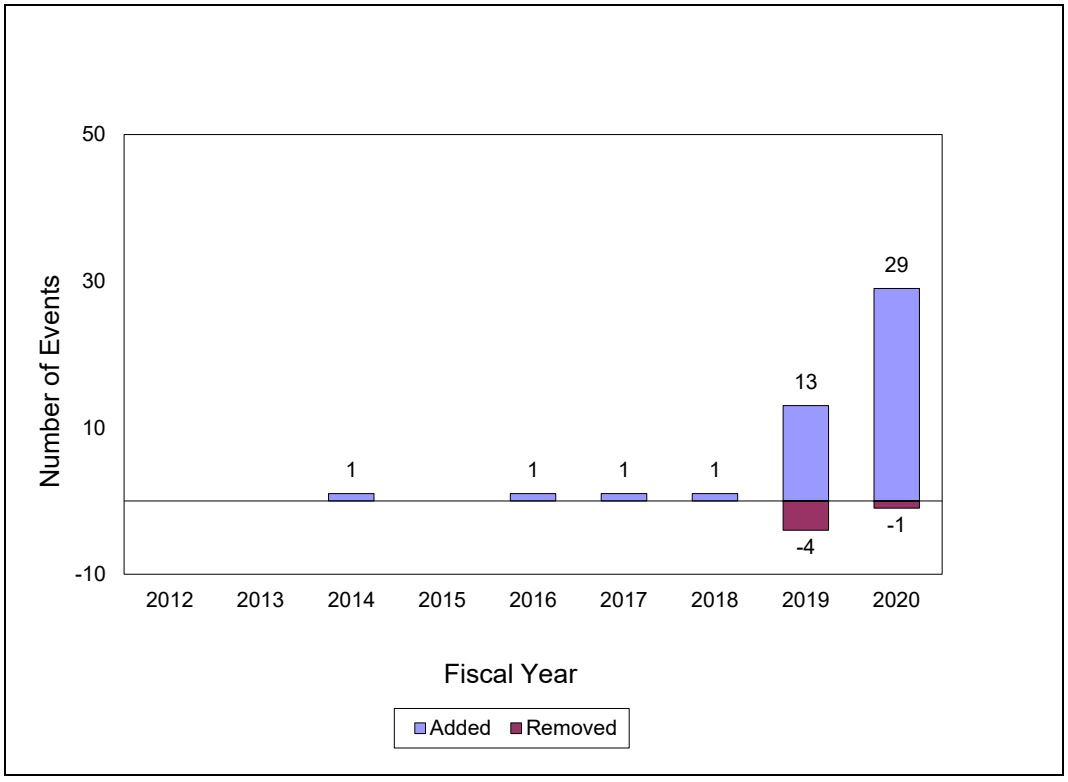

Figure D-1. Changes to All NMED Event Data

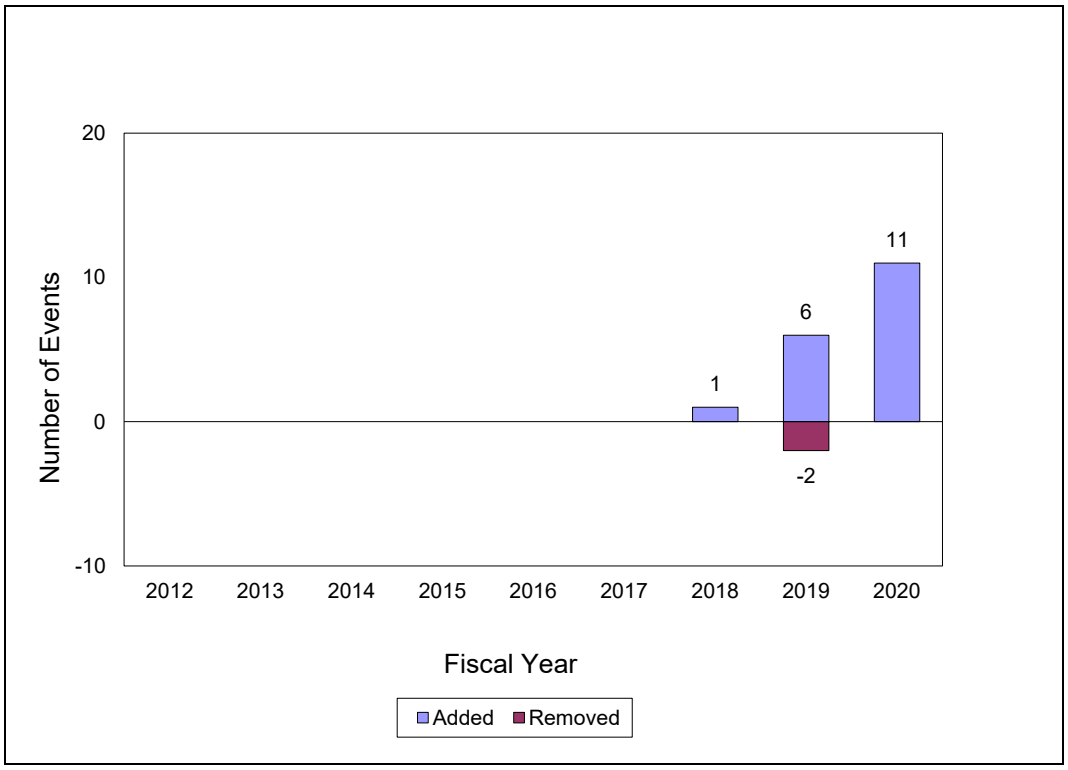

Figure D-2. Changes to LAS Data

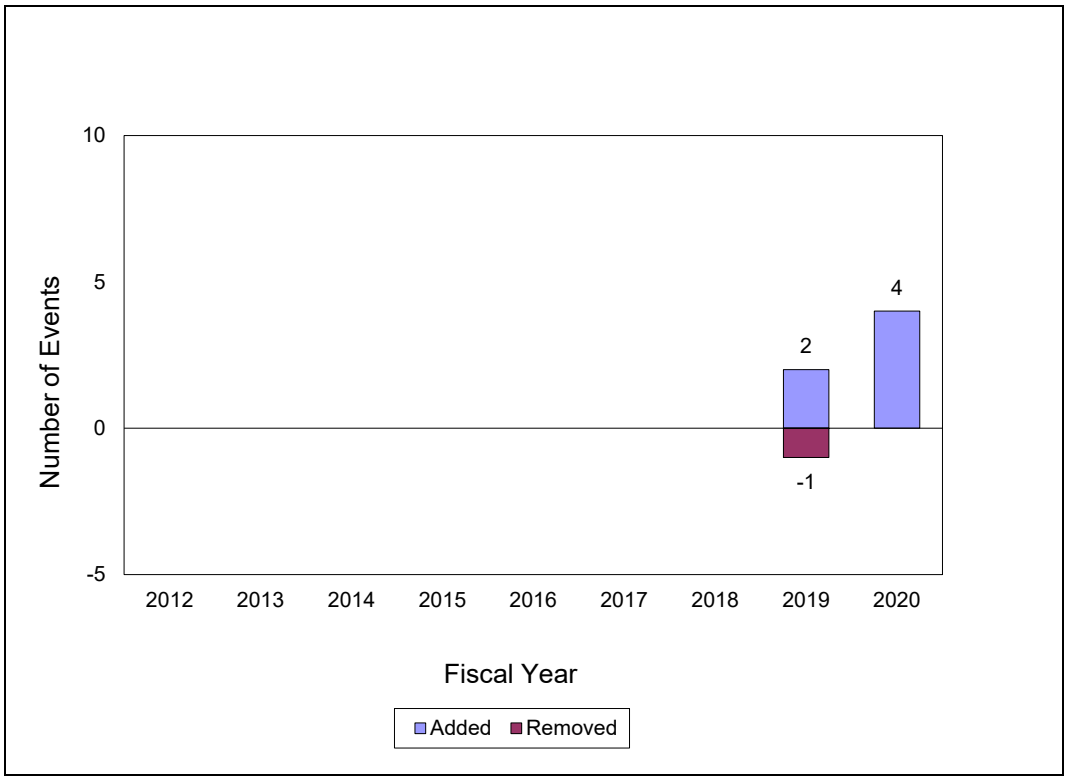

Figure D-3. Changes to MED Data

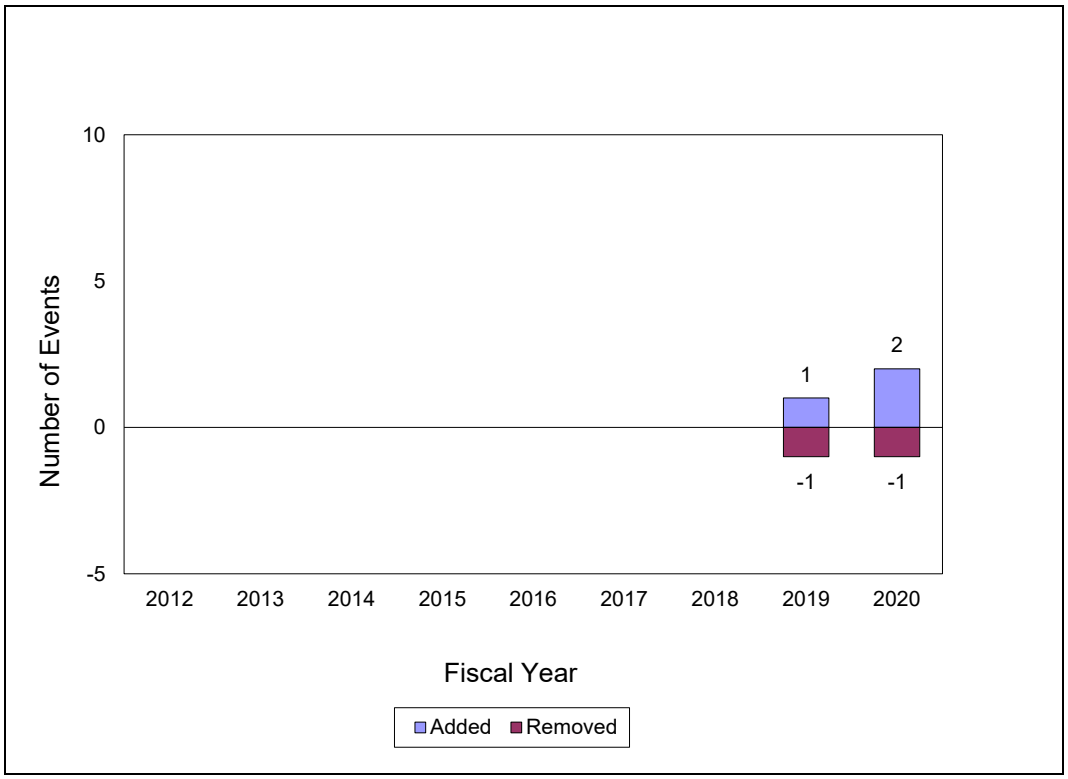

Figure D-4. Changes to EXP Data

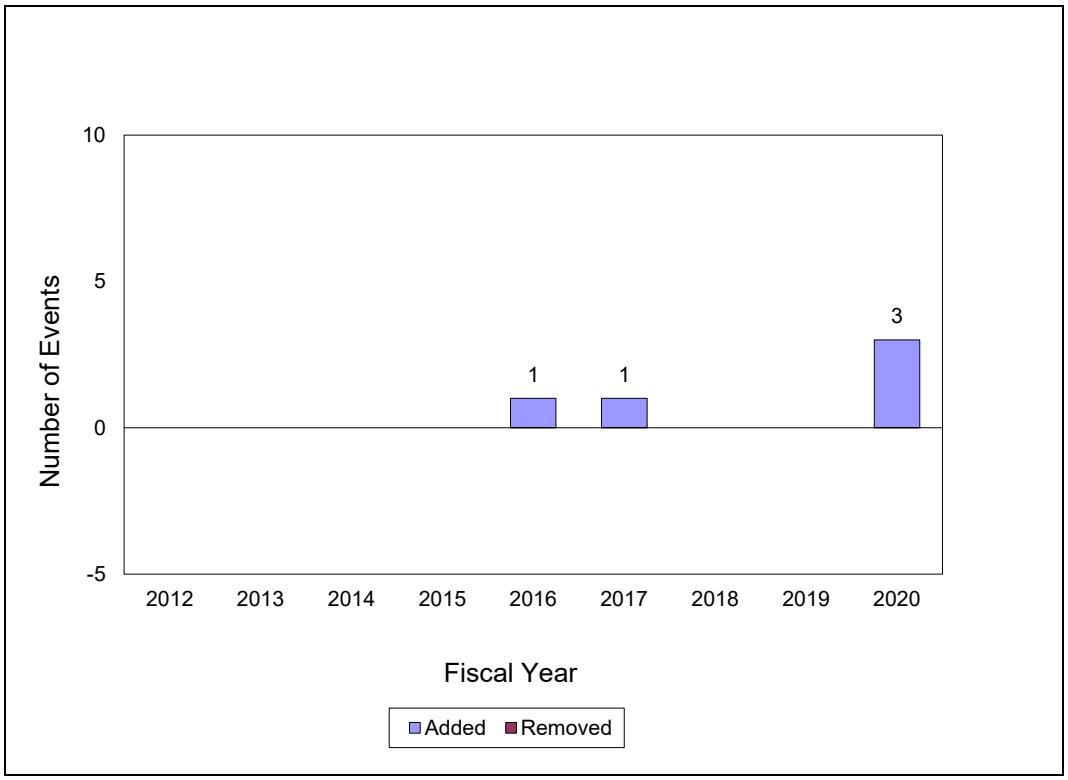

Figure D-5. Changes to RLM Data

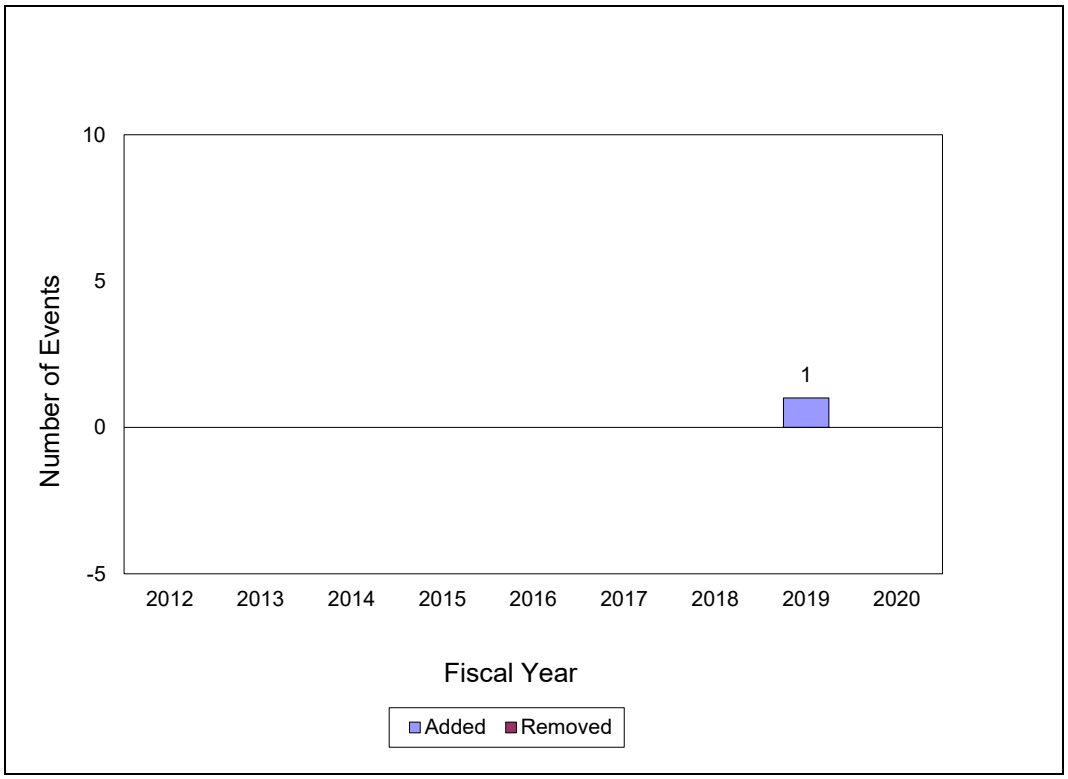

Figure D-6. Changes to LKS Data

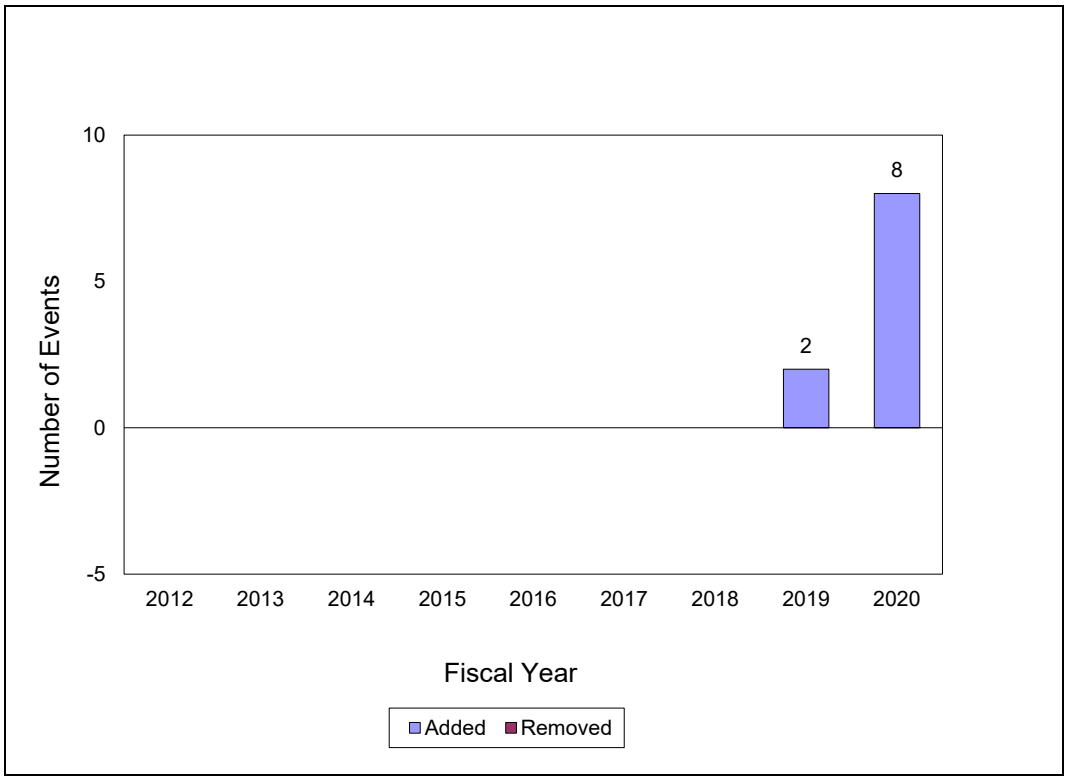

Figure D-7. Changes to EQP Data

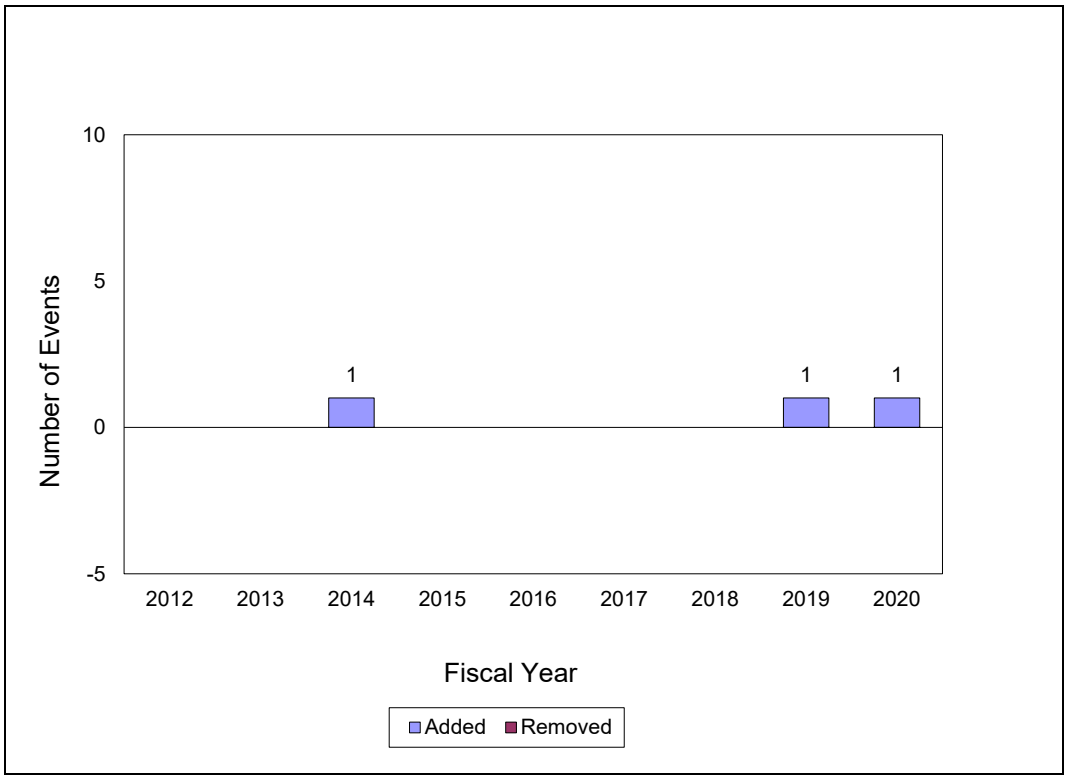

Figure D-8. Changes to TRS Data

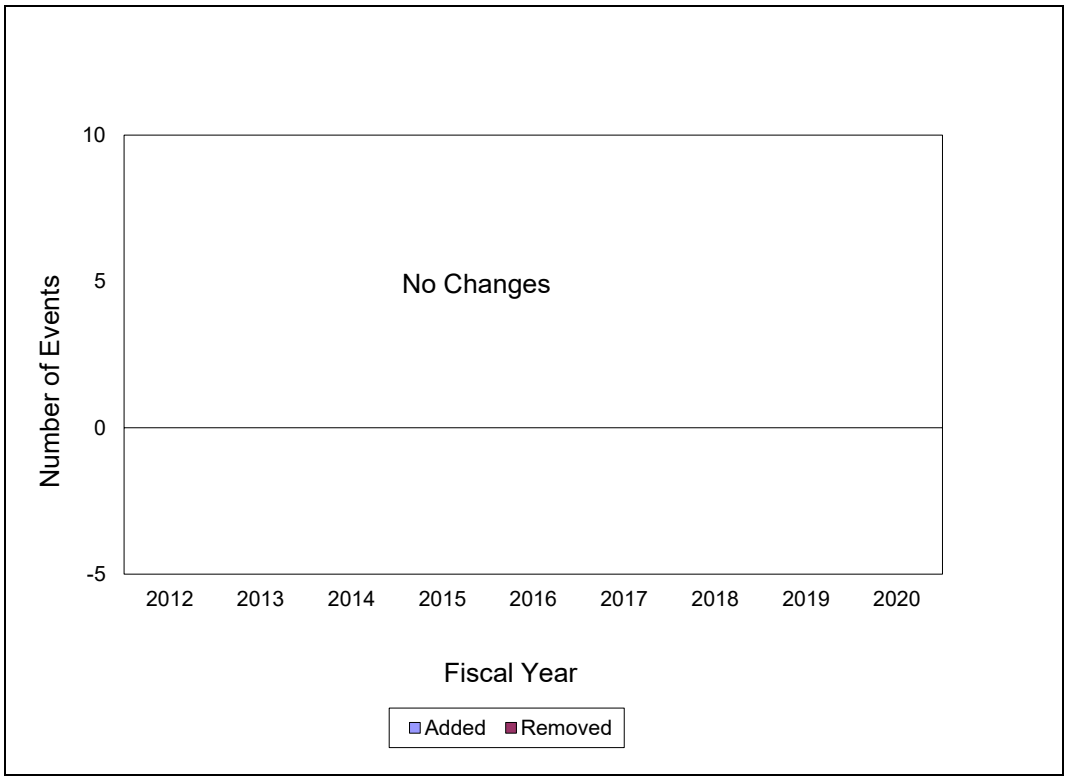

Figure D-9. Changes to OTH Data

Appendix E

Best Practice Concepts for Writing Medical Event Reports

Appendix E
Best Practice Concepts for Writing Medical Event Reports

Section 2.3 of this report covers Medical (and Embryo/Fetus or Nursing Child) events reported to the NRC. Medical event reports are made in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 35.3045, "Report and notification of a medical event."

Section 2.3 of this report also summarizes the overall trend of Medical events over the past 10-year period. Additionally, both the NRC staff and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) perform annual reviews of medical event reports to determine any trends or patterns, to identify generic issues or generic concerns, and to recognize any inadequacies or unreliability of specific equipment or procedures. The NRC staff and the ACMUI present their findings at biannual ACMUI meetings. The presentations from recent years are posted on the NRC Medical Uses Licensee Toolkit Webpage, https://www.nrc.gov/materials/miau/med-use-toolkit.html.

While medical events rarely result in patient harm, the purpose of medical event reporting is to identify the causes of the events in order to correct them, to prevent their recurrence, and to allow the NRC to notify other licensees of the events so they can avoid them. The information collected on medical events is invaluable in assessing trends or patterns, identifying generic issues or generic concerns, and recognizing any inadequacies or unreliability of specific equipment or procedures. The reported information is critical for initiating a timely and effective understanding as to why the event occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs.

In order to better support the trending reviews and the NRC's goal of identifying generic issues, the following best practice concepts and examples of thorough medical event reports is provided to help increase event report uniformity and consistency.

It is important to note that the medical event reporting requirements are provided in 10 CFR 35.3045(d)(1)(i-vii) and require a written report submitted to the appropriate NRC regional office within 15 days after discovery of the medical event. The best practice concepts provided below do not change these regulatory requirements and do not redefine the NRC's expectation of event reporting. Instead, these concepts are being provided for awareness and as a reference. The elements required for the 15-day report required under 10 CFR 35.3045(d)(1)(i-vii) are:

(i) The licensee's name,

(ii) The name of the prescribing physician,

(iii) A brief description of the event,

(iv) Why the event occurred,

(v) The effect, if any, on the individual(s) who received the administration,

(vi) What actions, if any, have been taken or are planned to prevent recurrence, and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

Guidance regarding the expectations of reporting medical events is provided in SA-300, "Reporting Material Events" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13053A346) and the "Handbook on Nuclear Material Event Reporting in the Agreement States Final Report March 2013" (ADAMS Accession No. ML13053A420).

The written report requirements in 35.3045(d)(1), in part, require why the event occurred (i.e., root cause) and what actions, if any, have been taken or are planned to prevent recurrence (i.e., corrective action).

However, the details submitted in medical event reports for why the event occurred (i.e., root cause) and what actions, if any, have been taken or are planned to prevent recurrence (i.e., corrective actions) range from minimal to a high-level of detailed information. Events that provide the minimal amount of information often lack a useful narrative to fully assess medical events as part of the NRC's event trending activities. Some best practice concepts to consider when writing medical event reports have been compiled below. However, these concepts are not required to be followed for meeting the 10 CFR 35.3045(d)(1)(i-vii) reporting requirements.

Best Practice Elements

Best practice elements to consider for the root cause analysis:

- What happened. Provide enough detail that an uninvolved individual would have a full understanding of the medical event, such as:
    - Including manufacturer or model of the device associated with the event, if applicable,
    - Including manufacturer or model of supporting equipment associated with the event, such as specific applicator or microcatheter,
    - Reporting both specifically what was prescribed as well as what was actually administered, including: radionuclide, activity, organs/tissues involved.
- When, in the process of radiation delivery, did the event occur?
- Who was present at the time of the medical event?
- What preceded the medical event?
- How did the medical event occur?
- What helped identify the medical event occurred?
- Who/what detected the medical event?
- For root causes identified as human error, be more specific with the exact error that occurred.

Best practice elements to consider for the corrective action:

- What are the short-term and long-term corrective actions?
- How are the corrective actions linked to the medical events?
- When are the corrective actions being implemented?
- What corrective actions may be relevant at a generic level for other procedures?
- Specifically identify if the corrective action involves a common industry wide practice or procedure.

Best practice elements to consider in general for the medical event report:

- Include relevant information provided by the manufacturer (when applicable).
- Include effective dose, or isotope and activity, and tissue volume information.
- Include medical and technical information about the event, including any adverse effects that are expected as a result of the event or a statement that no adverse effects are expected.

- Include as much relevant details as possible for the written report.
- Complete the final reporting as soon as possible.

Examples

NMED Item Number 200056 and Item Number 190237 are included as examples of NMED narratives resulting from well written medical event reports.

Item Number 200056 - Hospital X reported that, during a prostate brachytherapy procedure on 1/29/2020, all 76 I-125 brachytherapy seeds (Manufacturer Y model Z) were inadvertently implanted into the patient's bladder instead of the prostate. Each seed contained an activity of 12.95 MBq (350 μCi), for a total activity of 984.2 MBq (26.6 mCi). The prescribed dose to the prostate was 14,500 cGy (rad). A computed tomography (CT) scan of the patient's chest, abdomen, and pelvis was performed on 1/31/2020. There were 41 seeds identified in the bladder wall and fatty tissue surrounding the bladder. There were no seeds identified in the prostate, urethra, lungs, or other organs. The hospital assumed that patient expelled the remaining 35 seeds during urination at home. The patient, referring urologist, and oncologist were notified on 2/3/2020. The planned dose to the bladder was 7,500 cGy (rad). Preliminary calculations indicated the post-implant dose was 21,000 cGy (rad) to two cc of the bladder. However, the hospital's one-month, post-procedure estimated dose was 18,000 cGy (rad) to one cc of the bladder. The prostate base location coordinate may have inadvertently shifted and/or been misidentified prior to starting the implant procedure. Because fluoroscopy was not used to compare with the trans-rectal ultrasound image, the incorrect location would not have been identified. The hospital temporarily suspended its prostate seed implant program and performed an internal review. The cause of the event was failure to follow procedure or wrong procedure used. Corrective actions included updating the prostate implant program and performing appropriate training. The patient experienced urinary frequency, urgency, and nocturia. The patient's potential long-term effect is hemorrhagic cystitis. The South Carolina Department of Health & Environmental Control performed an investigation.

Item Number 190237 - Cancer Center X reported that a patient received a dose that was 87.6% greater than prescribed during one high dose rate (HDR) brachytherapy fraction administered on 5/21/2019. The patient was being treated using an HDR brachytherapy unit (Manufacturer Y model Z, serial A) and a 273.25 GBq (7.385 Ci) Ir-192 source (Manufacturer X model Y, serial Z). The patient was prescribed to receive 10 fractions, two per day for five days. The prescribed dose was 625 cGy (rad) per fraction, for a total dose of 6250 cGy (rad). However, during one fraction, the patient received a dose of 1,167.3 cGy (rad). After the pretreatment setup for this fraction was completed satisfactorily, including a time out, the treatment was commenced. During the test run of the dummy source to check the clearance of each channel, the system gave an "electronics defective" error and the treatment was aborted. The physicist confirmed that no dose had been delivered. The physicist then loaded the first treatment plan in the list (which was not the correct plan for this patient), viewed the pre-treatment report, and obtained the treatment code required to start a treatment delivery. The doctor then actuated the treatment. The physicist and doctor were actively monitoring the patient via CCTV when the physicist realized that he did not hear the system change to a different channel. He turned to the treatment console and recognized that all of the dwell times were in channel one and something was wrong. He interrupted the treatment and informed the doctor that the wrong treatment plan was delivered. The event occurred because no time out and no plan verification was performed after the aborted test. The patient was notified on 5/21/2019. Cancer Center X expected no harm to the patient. The overall treatment plan was modified to deliver a total dose of 6165 cGy (rad) over nine fractions. Several corrective actions were implemented. If there is an aborted treatment, the entire review process will be re-done to ensure there have been no changes to the patient setup or treatment plan parameters. The pretreatment report will be printed out and reviewed and compared to the approved treatment plan. The treatment console and CCTV will be monitored at all times that a patient is under care. Training will be performed to ensure the clinical team understands the updated time out and plan verification process.